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By: ~~**Senator Bromwell**~~ **Senators Bromwell, Astle, Della, Derr, Dorman, Hafer, Kelley, Madden, Roesser, Teitelbaum, and Trotter**
Introduced and read first time: January 22, 1998
Assigned to: Finance

Committee Report: Favorable with amendments
Senate action: Adopted with floor amendments
Read second time: March 2, 1998

CHAPTER_____

AN ACT concerning

Health Insurance - Medical Clinical Trials - Coverage

FOR the purpose of requiring certain insurers ~~and~~ , nonprofit health service plans, and health maintenance organizations to provide coverage for certain patient ~~costs~~ cost incurred as a result of a treatment being provided or studies being conducted in accordance with a clinical trial under certain circumstances; requiring certain insurers ~~and~~ , nonprofit health service plans, and health maintenance organizations 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; requiring an entity seeking coverage under this Act to post electronically and keep up-to-date a certain list; requiring certain insurers, nonprofit health service plans, and health maintenance organizations to report certain information to the Insurance Commissioner; requiring the Insurance Commissioner to make a certain summary report; requiring the Insurance Commissioner to create a certain workgroup; requiring the workgroup to undertake a certain study and present a certain report; providing for the applicability of this Act; providing for the effective date of this Act; and generally relating to requiring certain insurers ~~and~~ , nonprofit health service plans, and health maintenance organizations to provide coverage for certain patient ~~costs~~ cost incurred as a result of a treatment being provided or studies being conducted 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 15-826

Annotated Code of Maryland
(1997 Volume)

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

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

Article - Insurance

15-826.

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

(5) "MULTIPLE PROJECT ASSURANCE" MEANS A CONTRACT BETWEEN AN INSTITUTION AND THE FEDERAL DEPARTMENT OF HEALTH AND HUMAN SERVICES THAT DEFINES THE RELATIONSHIP OF THE INSTITUTION TO THE FEDERAL DEPARTMENT OF HEALTH AND HUMAN SERVICES AND SETS OUT THE RESPONSIBILITIES OF THE INSTITUTION AND THE PROCEDURES THAT WILL BE USED BY THE INSTITUTION TO PROTECT HUMAN SUBJECTS.

~~(4)~~ (6) "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)~~ (7) (I) "PATIENT COST" MEANS ~~ANY~~ THE COST OF A MEDICALLY NECESSARY HEALTH CARE SERVICE THAT IS INCURRED AS A RESULT OF THE TREATMENT BEING PROVIDED TO THE ~~PATIENT~~ MEMBER 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:

(1) 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 ~~.~~;AND

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

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

~~(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;~~

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

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

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

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

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

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

(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 APPLICATION;

(IV) THE FEDERAL DEPARTMENT OF VETERANS AFFAIRS;

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

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

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

(V) AN INSTITUTIONAL REVIEW BOARD OF AN INSTITUTION IN THE STATE WHICH HAS A MULTIPLE PROJECT ASSURANCE APPROVED BY THE OFFICE OF PROTECTION FROM RESEARCH RISKS OF THE NATIONAL INSTITUTES OF HEALTH;

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

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

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

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

~~(D)~~ (G) IN ~~ADDITION TO~~ CONJUNCTION WITH THE PROVISIONS OF SUBSECTION ~~(C)~~ (D) OF THIS SECTION, A POLICY OR PLAN SHALL PROVIDE COVERAGE FOR PATIENT ~~COSTS~~ COST 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, TO THE EXTENT THAT THE DRUGS OR DEVICES ARE NOT PAID FOR BY THE MANUFACTURER, DISTRIBUTOR, OR PROVIDER OF THAT DRUG OR DEVICE.

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

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

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

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

(II) THE ENTITY APPROVING THE TRIAL;

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

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

Article - Health - General

19-706.

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

SECTION 2. AND BE IT FURTHER ENACTED, That:

(a) On or before June 1 of each year, each insurer, nonprofit health service plan, and health maintenance organization subject to the requirements of this Act

shall submit to the Commissioner, on the form the Commissioner requires, a report that describes the clinical trials covered during the previous year.

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

SECTION 3. AND BE IT FURTHER ENACTED, That:

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

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

(c) At a minimum, the Workgroup shall:

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

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

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

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

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

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

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

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

(5) One representative of the National Institutes of Health;

(6) Four representatives, including two health plan medical directors licensed to practice medicine in this State, of health insurers, nonprofit health service plans, or health maintenance organizations licensed to do business in this State;

(7) One member of the general public; and

(8) The Insurance Commissioner or the Commissioner's designee.

(e) The Workgroup shall select a chairman from among its members.

(f) Staffing for the Workgroup shall be provided by the Maryland Insurance Administration.

(g) The Workgroup shall present a preliminary report on the results of its study, including findings and recommendations, to the Senate Finance Committee and the House Economic Matters Committee, and, in accordance with § 2-1246 of the State Government Article, the General Assembly, on or before July 1, 2000. If the Workgroup requests an additional year to complete its work, the Workgroup shall present a final report on or before July 1, 2001.

SECTION 4. AND BE IT FURTHER ENACTED, That this Act shall apply to all new policies or health benefit plans issued or delivered in the State on or after January 1, 1999 and to the renewal of all policies in effect before that date, except that any policy or health benefit plan in effect before January 1, 1999 shall comply with the provisions of this Act no later than January 1, 2000.

SECTION 5. AND BE IT FURTHER ENACTED, That Section 3 of this Act shall take effect July 1, 1998.

SECTION 6. AND BE IT FURTHER ENACTED, That, subject to Section 5 of this Act, this Act shall take effect ~~October 1, 1998~~ January 1, 1999.