Unofficial Copy **1998 Regular Session**
HB0045/573577/1

BY: Economic Matters Committee

AMENDMENTS TO HOUSE BILL NO. 45
(First Reading File Bill)

AMENDMENT NO. 1

On page 1, in the sponsor line, strike "and Harrison" and substitute "Harrison, Busch, Gordon, Boston, Donoghue, Exum, Frank, Fulton, Goldwater, Kirk, Love, and Pendergrass".

AMENDMENT NO. 2

On page 1, in line 3, strike "and" and substitute a comma; in the same line, after "plans" insert ", and health maintenance organizations"; in line 4, strike "costs" and substitute "cost"; in line 5, after "provided" insert "or studies being conducted"; in line 6, strike "and" and substitute a comma; in the same line, after "plans" insert ", and health maintenance organizations"; in line 9, after "terms;" insert "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 application of this Act; providing for the effective date of this Act;"; in line 10, strike "and" and substitute a comma; in the same line, after "plans" insert ", and health maintenance organizations"; in the same line, strike "costs" and substitute "cost"; in line 11, after "provided" insert "or studies being conducted"; and after line 18, insert:

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

AMENDMENT NO. 3

On page 2, after line 9 insert:

(Over)

"(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 CONTRACT" 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.";

in lines 10 and 14, strike "(4)" and "(6)", respectively, and substitute "(6)" and "(7)", respectively; strike in their entirety lines 11 through 13, inclusive; in line 14, strike "ANY" and substitute "THE"; in line 16, strike "PATIENT" and substitute "MEMBER"; in line 26, strike "OR PLAN" and substitute ", PLAN, OR CONTRACT"; in line 27, after "TO" insert ":

(1)";

and in line 30, after "STATE" insert "; 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, PLAN, OR CONTRACT PAID FOR UNDER TITLE XVIII OR TITLE XIX OF THE SOCIAL SECURITY ACT".

AMENDMENT NO. 4

On pages 2 and 3, strike in their entirety the lines beginning with line 31 on page 2 through line 4 on page 3, inclusive, and substitute:

"(D) A POLICY, PLAN, OR CONTRACT 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;".

On page 3, in line 5, strike "ACCORDANCE WITH"; strike in their entirety lines 12 through 17, inclusive, and substitute:

"OR

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

in lines 18, 21, and 23, strike "(4)", "(5)", and "(6)", respectively, and substitute "(3)", "(4)", and "(5)", respectively; strike beginning with "PROVIDING" in line 19 down through "TRAINING" in line 20 and substitute "CAPABLE OF DOING SO BY VIRTUE OF THEIR EXPERIENCE, TRAINING, AND VOLUME OF PATIENTS TREATED TO MAINTAIN EXPERTISE"; in line 25, strike "EFFICACIOUS" and substitute "EFFECTIVE"; in the same line, after "THE" insert "NONINVESTIGATIONAL"; after line 25, insert:

"(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.";

in line 26, strike "ADDITION TO" and substitute "CONJUNCTION WITH"; in the same line, strike "(C)" and substitute "(D)"; in lines 26 and 31, strike "(D)" and "(E)", respectively, and substitute "(G)" and "(I)", respectively; in line 27, strike "POLICY OR PLAN" and substitute "POLICY, PLAN, OR CONTRACT"; in the same line, strike "COSTS" and substitute "COST"; in line 30, after "CONDITION" insert ", TO THE EXTENT THAT THE DRUGS OR DEVICES ARE NOT PAID FOR BY THE MANUFACTURER, DISTRIBUTOR, OR PROVIDER OF THAT DRUG OR DEVICE.

(H) (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";

and after line 32, insert:

"Article - Health - General

19-706.

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

AMENDMENT NO. 5

On page 3, strike in their entirety lines 33 and 34, inclusive, and substitute:

"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 Insurance Commissioner, on the form the Insurance Commissioner requires, a report that describes the clinical trials covered during the previous year.

(b) The Insurance 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, contracts, or health benefit plans issued or delivered in the State on or after January 1, 1999 and to the renewal of all policies, contracts, or health benefit plans in effect before that date, except that any policy, contract, 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 January 1, 1999.".