Unofficial Copy C3 1999 Regular Session 9lr0905 CF 9lr0665

By: Delegate Krysiak

Introduced and read first time: January 25, 1999 Assigned to: Economic Matters

A BILL ENTITLED

1 AN ACT concerning

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Health Insurance - Medical Clinical Trials - Coverage

3 FOR the purpose of requiring certain insurers, nonprofit health service plans, and

- 4 health maintenance organizations to provide coverage under certain
- 5 circumstances for certain patient cost incurred as a result of treatment being
- 6 provided in a Phase I clinical trial for a life-threatening condition other than
- 7 cancer; providing for the application of this Act; and generally relating to
- 8 coverage for patient cost incurred as a result of a treatment being provided in
- 9 accordance with a clinical trial.

10 BY repealing and reenacting, with amendments,

11 Article - Insurance

- 12 Section 15-827
- 13 Annotated Code of Maryland
- 14 (1997 Volume and 1998 Supplement)

15 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF

16 MARYLAND, That the Laws of Maryland read as follows:

17

Article - Insurance

18 15-827.

19 (a) (1) In this section the following words have the meanings indicated.

20 (2) (i) "Cooperative group" means a formal network of facilities that

21 collaborate on research projects and have an established NIH-approved Peer Review

22 Program operating within the group.

23	(ii)	"Cooperative group" includes:	
24		1.	the National Cancer Institute Clinical Cooperative Group;
2526 Oncology Program;		2.	the National Cancer Institute Community Clinical

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1	3. the AIDS Clinical Trials Group; and						
2	4. the Community Programs for Clinical Research in AIDS.						
3	(3) "FDA" means the federal Food and Drug Administration.						
4 5 holde 6 holde	(4) "Member" means a policyholder, subscriber, insured, or certificate or a covered dependent of a policyholder, subscriber, insured, or certificate						
7 (5) "Multiple project assurance contract" means a contract between an 8 institution and the federal Department of Health and Human Services that defines 9 the relationship of the institution to the federal Department of Health and Human 10 Services and sets out the responsibilities of the institution and the procedures that 11 will be used by the institution to protect human subjects.							
12	(6) "NIH" means the National Institutes of Health.						
	13(7)(i)"Patient cost" means the cost of a medically necessary health14care service that is incurred as a result of the treatment being provided to the15member for purposes of the clinical trial.						
16	(ii) "Patient cost" does not include:						
17	1. the cost of an investigational drug or device;						
 18 2. the cost of nonhealth care services that a patient may be 19 required to receive as a result of the treatment being provided for purposes of the 20 clinical trial; 							
21 22 with	3. costs associated with managing the research associated e clinical trial; or						
23 24 plan,	4. costs that would not be covered under the patient's policy, contract for noninvestigational treatments.						
25 (This section applies to:						
28 expe	 (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 						
	30 (2) health maintenance organizations that provide hospital, medical, 31 surgical, or pharmaceutical benefits to individuals or groups under contracts that are 32 issued or delivered in the State.						
33 (This section does not apply to a policy, plan, or contract paid for under Title						

33 (c) This section does not apply to a policy, plan, or contract paid for under Title
 34 XVIII or Title XIX of the Social Security Act.

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1 2	1 (d) A policy, plan, or contract subject to this section shall provide coverage for 2 patient cost to a member in a clinical trial, as a result of:						
3		(1)	treatmen	nt provided for a life-threatening condition; or			
4		(2)	preventi	ion, early detection, and treatment studies on cancer.			
5	(e)	The cov	verage under subsection (d) of this section shall be required if:				
6 7	conducted ir	(1) n a Phase	(i) I, Phase	the treatment is being provided or the studies are being II, Phase III, or Phase IV clinical trial for cancer; or			
8 9	III, or Phase	IV clinio	(ii) cal trial fo	the treatment is being provided in a PHASE I, Phase II, Phase or any other life-threatening condition;			
10	1	(2)	the treat	tment is being provided in a clinical trial approved by:			
11			(i)	one of the National Institutes of Health;			
12			(ii)	an NIH cooperative group or an NIH center;			
13			(iii)	the FDA in the form of an investigational new drug application;			
14			(iv)	the federal Department of Veterans Affairs; or			
	which has a			an institutional review board of an institution in the state assurance contract approved by the Office of Protection ational Institutions of Health;			
				lity and personnel providing the treatment are capable of berience, training, and volume of patients treated to			
21 22	and	(4)	there is	no clearly superior, noninvestigational treatment alternative;			
				lable clinical or preclinical data provide a reasonable will be at least as effective as the noninvestigational			
 26 [(f) The coverage under subsection (d) of this section may be provided on a case 27 by case basis if the treatment is being provided in a Phase I clinical trial for any 28 life-threatening condition other than cancer.] 							
29 30		(F) , or cont		nction with the provisions of subsection (d) of this section, a provide coverage for patient cost incurred for drugs and			

20 policy, plan, or contract shall provide coverage for patient cost incurred for drugs and 31 devices that have been approved for sale by the FDA whether or not the FDA has 32 approved the drug or device for use in treating the patient's particular condition, to 33 the extent that the drugs or devices are not paid for by the manufacturer, distributor, 34 or provider of that drug or device.

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1 [(h)] (G) (1) An entity seeking coverage for treatment in a clinical trial 2 approved by an institutional review board under subsection (e)(2)(v) of this section 3 shall post electronically and keep up-to-date a list of the clinical trials meeting the 4 requirements of subsections (d) and (e) of this section.

5 (2) The list shall include, for each clinical trial:

6 (i) the phase for which the trial is approved;

7 (ii) the entity approving the trial;

(iv)

8 (iii) whether the trial is for treatment of cancer or another 9 life-threatening disease and, if not cancer, the particular disease; and

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the estimated number of participants in the trial.

11 [(i)] (H) This section may not be construed to affect compliance with § 15-804 12 of this subtitle regarding coverage for off-label use of drugs.

13 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall apply to all 14 new policies, contracts, or health benefit plans issued or delivered in the State on or 15 after July 1, 1999, and to the renewal of all policies, contracts, or health benefit plans 16 in effect before that date, except that any policy, contract, or health benefit plan in 17 effect before July 1, 1999, shall comply with the provisions of this Act no later than 18 January 1, 2000.

19 SECTION 3. AND BE IT FURTHER ENACTED, That, subject to Section 2 of 20 this Act, this Act shall take effect July 1, 1999.

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