

HOUSE BILL 109

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1999 Regular Session  
9r0905  
CF 9r0665

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By: **Delegate Krysiak**

Introduced and read first time: January 25, 1999

Assigned to: Economic Matters

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A BILL ENTITLED

1 AN ACT concerning

2 **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;

25 2. the National Cancer Institute Community Clinical

26 Oncology Program;



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) treatment provided for a life-threatening condition; or

4 (2) prevention, early detection, and treatment studies on cancer.

5 (e) The coverage under subsection (d) of this section shall be required if:

6 (1) (i) the treatment is being provided or the studies are being  
7 conducted in a Phase I, Phase II, Phase III, or Phase IV clinical trial for cancer; or

8 (ii) the treatment is being provided in a PHASE I, Phase II, Phase  
9 III, or Phase IV clinical trial for any other life-threatening condition;

10 (2) the treatment 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

15 (v) an institutional review board of an institution in the state  
16 which has a multiple project assurance contract approved by the Office of Protection  
17 from Research Risks of the National Institutions of Health;

18 (3) the facility and personnel providing the treatment are capable of  
19 doing so by virtue of their experience, training, and volume of patients treated to  
20 maintain expertise;

21 (4) there is no clearly superior, noninvestigational treatment alternative;  
22 and

23 (5) the available clinical or preclinical data provide a reasonable  
24 expectation that the treatment will be at least as effective as the noninvestigational  
25 alternative.

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 [(g)] (F) In conjunction with the provisions of subsection (d) of this section, a  
30 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.

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;

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

10                    (iv)    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.