

# HOUSE BILL 456

C3

9lr2368

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By: **Delegate Morhaim**

Introduced and read first time: February 4, 2009

Assigned to: Health and Government Operations

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## A BILL ENTITLED

1 AN ACT concerning

2 **Health Insurance – Coverage for Off-Label Use of Drugs –**  
3 **Standard Reference Compendia**

4 FOR the purpose of altering the definition of “standard reference compendia” for  
5 purposes of health insurance coverage for off-label use of drugs; and generally  
6 relating to coverage for off-label use of drugs under health insurance.

7 BY repealing and reenacting, with amendments,  
8 Article – Insurance  
9 Section 15–804  
10 Annotated Code of Maryland  
11 (2006 Replacement Volume and 2008 Supplement)

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

14 **Article – Insurance**

15 15–804.

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

17 (2) “Medical literature” means scientific studies published in a  
18 peer-reviewed national professional medical journal.

19 (3) “Off-label use” means the prescription of a drug for a treatment  
20 other than those treatments stated in the labeling approved by the federal Food and  
21 Drug Administration.

22 (4) “Standard reference compendia” means:

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EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



- 1 (i) [the United States Pharmacopeia Drug Information;  
2 (ii) the American Medical Association Drug Evaluations; and  
3 (iii)] the American Hospital Formulary Service Drug Information;

4 (II) THE NATIONAL COMPREHENSIVE CANCER NETWORK  
5 DRUGS & BIOLOGICS COMPENDIUM;

6 (III) THE THOMSON MICROMEDEX DRUGDEX;

7 (IV) THE ELSEVIER GOLD STANDARD'S CLINICAL  
8 PHARMACOLOGY; OR

9 (V) ANY OTHER AUTHORITATIVE COMPENDIA AS  
10 RECOGNIZED PERIODICALLY BY THE FEDERAL SECRETARY OF HEALTH AND  
11 HUMAN SERVICES OR THE COMMISSIONER.

12 (b) This section does not:

13 (1) alter any law that limits the coverage of drugs that have not been  
14 approved by the federal Food and Drug Administration;

15 (2) require coverage of a drug if the federal Food and Drug  
16 Administration has determined use of the drug to be contraindicated; or

17 (3) require coverage of experimental drugs not approved for any  
18 indication by the federal Food and Drug Administration.

19 (c) (1) This subsection applies to each health insurance policy or contract  
20 that is delivered or issued for delivery in the State to an employer or individual on a  
21 group or individual basis, including a contract issued by a health maintenance  
22 organization.

23 (2) A policy or contract subject to this subsection that provides  
24 coverage for drugs may not exclude coverage of a drug for an off-label use of the drug  
25 if the drug is recognized for treatment in any of the standard reference compendia or  
26 in the medical literature.

27 (3) Coverage of a drug required by this subsection also includes  
28 medically necessary services associated with the administration of the drug.

29 (d) The Commissioner may direct a person, including a health maintenance  
30 organization, that issues a health insurance policy or contract to make payments  
31 required by this section.

1           (e)    (1)    The Secretary of Health and Mental Hygiene shall appoint a panel  
2 of medical experts to review the off-label use of drugs not included in any of the  
3 standard reference compendia or in the medical literature and to advise the Secretary  
4 whether a particular off-label use of a drug is medically appropriate.

5                   (2)    The panel consists of:

6                           (i)    three medical oncologists chosen by the State Medical  
7 Oncology Association;

8                           (ii)   two specialists in the management of AIDS patients chosen  
9 by the State AIDS medical provider organizations;

10                          (iii)   one specialist in heart disease appointed by the University of  
11 Maryland Medical System; and

12                          (iv)   one physician chosen by the Medical and Chirurgical  
13 Faculty.

14           (3)    The panel shall make recommendations periodically and whenever  
15 the Secretary of Health and Mental Hygiene is notified of a particular dispute about  
16 payment for an off-label use of a drug.

17           (4)    Within 30 days after the panel's recommendations, the Secretary  
18 shall submit a written report on the recommendations to the Commissioner.

19           SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect  
20 October 1, 2009.