SENATE BILL 985

C3 9lr3102
CF HB 456

By: **Senator Garagiola**
Introduced and read first time: February 25, 2009
Assigned to: Rules

A BILL ENTITLED

AN ACT concerning

Health Insurance – Coverage for Off–Label Use of Drugs – Standard Reference Compendia

FOR the purpose of altering the definition of "standard reference compendia" for purposes of health insurance coverage for off–label use of drugs; and generally relating to coverage for off–label use of drugs under health insurance.

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

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

Article – Insurance

15–804.

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

(2) "Medical literature" means scientific studies published in a peer–reviewed national professional medical journal.

(3) "Off–label use" means the prescription of a drug for a treatment other than those treatments stated in the labeling approved by the federal Food and Drug Administration.

(4) "Standard reference compendia" means:

EXPLANATION: **CAPITALS INDICATE MATTER ADDED TO EXISTING LAW**.
[Brackets**]** indicate matter deleted from existing law.

(i) **[**the United States Pharmacopeia Drug Information;

(ii) the American Medical Association Drug Evaluations; and

(iii)**]** the American Hospital Formulary Service Drug Information**;**

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

(III) THE THOMSON MICROMEDEX DRUGDEX;

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

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

(b) This section does not:

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

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

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

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

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

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

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

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

(2) The panel consists of:

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

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

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

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

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

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

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