

House Bill No. 351

AN ACT concerning

Health Maintenance Organizations – Off-Label Use of Drugs

FOR the purpose of altering ~~a provision~~ provisions a provision of law to establish that a health maintenance organization may not exclude coverage of a drug for a particular indication on the ground that the drug has not been approved by the federal Food and Drug Administration for that indication if the drug is recognized for treatment of the indication in certain reference compendia or certain medical literature; requiring the Secretary of Health and Mental Hygiene to submit a certain written report to the Insurance Commissioner; and authorizing the ~~Secretary of Health and Mental Hygiene~~ Insurance Commissioner to direct a health maintenance organization to make payments required under this Act.

BY repealing and reenacting, with amendments,
Article 48A – Insurance Code
Section 490AA
Annotated Code of Maryland
(1994 Replacement Volume and 1994 Supplement)

BY repealing and reenacting, with amendments,
Article – Health – General
Section 19-706(i)
Annotated Code of Maryland
(1990 Replacement Volume and 1994 Supplement)

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

Article 48A – Insurance Code

490AA.

(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 of drugs” means when drugs are prescribed for treatments other than those stated in the labeling approved by the federal Food and Drug Administration.

(4) “Standard reference compendia” means:

- (i) The United States Pharmacopeia Drug Information;
- (ii) The American Medical Association Drug Evaluations; or
- (iii) The American Hospital Formulary Service Drug Information.