

and requires Medicaid agencies to pay for off-label use of drugs prescribed for Medicaid patients if the use is stated in any of these sources; and the Omnibus Budget Reconciliation Act of 1993 applies the same criteria and coverage to Medicare patients; and

WHEREAS, Ten states have passed legislation similar to this Act; and

WHEREAS, Use of FDA approved drugs for off-label indications provides efficacious drugs at a lower cost; to require that all appropriate uses of a drug undergo approval by the FDA would substantially increase the cost of drugs, and delay or even deny patients' ability to obtain medically effective treatment; FDA approval for each use would require substantial expenditure and time to undergo the clinical trials necessary to obtain FDA approval, particularly when a drug is off patent and in generic production, and consequently is available at a lower price; once a drug is in generic production by multiple manufacturers, it is not economically feasible for a manufacturer to incur the cost of FDA approval; and

WHEREAS, Reimbursement for off-label indications of FDA approved drugs is necessary to conform to the way in which appropriate medical treatment is provided; to make needed drugs available to patients, and to contain health care costs; now, therefore,

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

**Article 48A – Insurance Code**

490W.

(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.

(B) (1) EACH CONTRACT OR POLICY OF HEALTH INSURANCE DELIVERED OR ISSUED FOR DELIVERY WITHIN THE STATE TO AN EMPLOYER OR AN INDIVIDUAL ON A GROUP OR INDIVIDUAL BASIS THAT PROVIDES COVERAGE FOR DRUGS MAY NOT EXCLUDE COVERAGE OF A DRUG FOR A PARTICULAR INDICATION ON THE GROUND THAT THE DRUG HAS NOT BEEN APPROVED BY THE FEDERAL