

experts to review off-label uses of drugs and to advise the Secretary about certain off-label use; providing for the construction of this Act; and generally relating to coverage in health insurance contracts and policies for off-label uses of drugs.

BY adding to

Article 48A – Insurance Code

Section 490W

Annotated Code of Maryland

(1991 Replacement Volume and 1993 Supplement)

Preamble

WHEREAS, The citizens of Maryland rely on health insurance to cover the cost of obtaining health care and it is essential that the citizens' expectation that their health care costs will be paid by their insurance policies is not disappointed and that they obtain the coverage necessary and appropriate for their care within the terms of their insurance policies; and

WHEREAS, Some insurers deny payment for drugs that have been approved by the federal Food and Drug Administration (FDA) when the drugs are used for indications other than those stated in the labeling approved by the FDA (off-label use) while other insurers with similar coverage terms do pay for off-label use; and

WHEREAS, Denial of payment for off-label use can interrupt or effectively deny access to necessary and appropriate treatment for a person being treated for a life-threatening illness; and

WHEREAS, Equity among employers who obtain insurance coverage for their employees and fair competition among insurance companies require that insurance companies assure citizens reimbursement for drugs in the same way and in the way citizens expect; and

WHEREAS, Off-label use of an FDA approved drug is legal when prescribed in a medically appropriate way and is often necessary to provide needed care, with approximately 50% of cancer drug treatment for off-label indications; and

WHEREAS, The FDA and the federal Department of Health and Human Services recognize the wide variety of effective uses of FDA approved drugs for off-label indications; and

WHEREAS, Information on the appropriate off-label use of FDA approved drugs is obtained from compendia published by the United States Pharmacopeial Convention, the American Medical Association, and the American Society of Hospital Pharmacists; in addition, scientific studies of off-label use of drugs published in recognized peer-reviewed professional journals provide information on appropriate use of drugs for off-label indications; the Omnibus Budget Reconciliation Act of 1990 recognizes these three compendia and peer-reviewed literature as appropriate sources for reimbursement