SB480

136053-1

By Senator Bedford

RFD: Banking and Insurance

First Read: 05-APR-12

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SYNOPSIS: To repeal portions of Title 27 of the Code of Alabama 1975.

A BILL

TO BE ENTITLED

AN ACT

Relating to the Alabama Insurance Code, to repeal the following:

27-1-10.1. (a) The Legislature finds and declares the following: (1) The citizens of this state rely upon 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. (2) Some insurers deny payment for drugs that have been approved by the Federal Food and Drug Administration, hereafter referred to as FDA, when the drugs

are used for indications other than those stated in the labelling approved by the FDA, off-label use, while other insurers with similar coverage terms do pay for off-label use. (3) 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. (4) 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. (5) Off-label use of an FDA-approved drug is legal when prescribed in a medically appropriate manner and is often necessary to provide needed care. Approximately 50% of cancer drug treatment is for off-label indications. 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. Information on the appropriate off-label use of FDA-approved drugs is obtained from compendia published by the United States Pharmacopoeial 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 and requires Medicaid agencies to pay for off-label use of drugs prescribed for Medicaid patients if the use is stated in any of such sources. The Omnibus Budget Reconciliation Act of 1993 applies the same criteria and coverage to Medicare patients. (6) 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. This is particularly the case 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. (7) 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. (b) The following words and phrases used in this section shall have the following meanings: (1) CONTRAINDICATION. The potential for, or the occurrence of, an undesirable alteration of the therapeutic effect of a given prescription because of the presence, in the patient for whom it is prescribed, of a

disease condition or the potential for, or the occurrence of, a clinically significant adverse effect of the drug on the patient's disease condition. (2) INDICATION. Any symptom, cause, or occurrence in a disease which points out its cause, diagnosis, course of treatment, or prognosis. (3) INSURANCE POLICY. An individual, group, blanket, or franchise insurance policy, insurance agreement, or group hospital service contract providing for hospital, medical, surgical, or pharmaceutical services. (4) MEDICAL LITERATURE. Published scientific studies published in any peer-reviewed national professional journal. (5) STANDARD REFERENCE COMPENDIA. Any of the following: a. The United States Pharmacopeia Drug Information. b. The American Medical Association Drug Evaluations. c. The American Hospital Formulary Service Drug Information. (c)(1) Title 27, or any other provision of law, rule, or regulation to the contrary notwithstanding, it is specifically provided that: a. No insurance policy which provides coverage for drugs shall 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 that indication in one of the standard reference compendia, or in the medical literature, or by the Commissioner of Insurance. b. Coverage of a drug required by this section shall also include medically necessary services associated with the administration of the drug. (2) This section shall

not be construed to alter existing law with regard to provisions limiting the coverage of drugs that have not been approved by the Federal Food and Drug Administration. (3) This section shall not be construed to require coverage for any drug when the Federal Food and Drug Administration has determined its use to be contraindicated. (4) This section shall not be construed to require coverage for experimental drugs not otherwise approved for any indication by the Federal Food and Drug Administration. (5) The Commissioner of Insurance may direct any person who issues an insurance policy to make payments required by this section. (6) Nothing in this section shall be construed, expressly or by implication, to create, impair, alter, limit, modify, enlarge, abrogate, or prohibit reimbursement for drugs used in the treatment of any other disease or condition.

27-1-11. Whenever the terms "physician" and/or "doctor" are used in any policy of health or accident insurance issued in this state or in any contract for the provision of health care, services, or benefits issued by any health, medical or other service corporation existing under, and by virtue of any laws of this state, said terms shall include within their meaning those persons licensed under and in accordance with Chapter 9 of Title 34 in respect to any care, services, procedures or benefits covered by said policy of insurance or health care contract which the said persons are licensed to perform, any provisions in any such policy of

insurance or health care contract to the contrary notwithstanding. This section shall be applicable to all policies in this state, regardless of date of issue, on October 10, 1975.

BE IT ENACTED BY THE LEGISLATURE OF ALABAMA:

Section 1. Sections 27-1-1 to 27-1-11, Code of Alabama 1975, are repealed.

Section 2. This act shall become effective immediately following its passage and approval by the Governor, or its otherwise becoming law.