Unofficial Copy 2002 Regular Session
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By: **Senator Frosh**
Introduced and read first time: January 31, 2002
Assigned to: Finance

A BILL ENTITLED

AN ACT concerning

Prescription Drug Discounts and Rebates - Additional Authority

FOR the purpose of authorizing the Secretary of Health and Mental Hygiene to negotiate discount prices or rebates for prescription drugs; authorizing drug manufacturers or labelers that sell prescription drugs in the State to negotiate supplemental rebates for the Maryland Medical Assistance Program over those required by federal law; requiring the Secretary, when negotiating rebate terms, to consider certain information on prescription drug prices, discounts, and rebates; authorizing the Secretary to review whether to place a manufacturer's or labeler's products on a prior authorization list, or any other State-authorized formulary, if certain terms or rebates are not favorable to the State; requiring that conditions for prior authorization meet those established under federal law; requiring the Department to release the names of manufacturers and labelers that do not enter into rebate agreements; requiring the Secretary to adopt certain regulations; and generally relating to the implementation of a supplemental prescription drug discount program.

BY adding to
Article - Health - General
Section 15-124.3
Annotated Code of Maryland
(2000 Replacement Volume and 2001 Supplement)

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

Article - Health - General

15-124.3.

(A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE MEANINGS INDICATED.

(2) "LABELER" MEANS AN ENTITY OR PERSON THAT RECEIVES PRESCRIPTION DRUGS FROM A MANUFACTURER OR WHOLESALER AND REPACKAGES

THOSE DRUGS FOR LATER RETAIL SALE, AND THAT HAS A LABELER CODE FROM THE FEDERAL FOOD AND DRUG ADMINISTRATION.

(3) "MANUFACTURER" MEANS ANY ENTITY THAT IS ENGAGED IN:

(I) THE PRODUCTION, PREPARATION, PROPAGATION, COMPOUNDING, CONVERSION, OR PROCESSING OF PRESCRIPTION DRUG PRODUCTS EITHER DIRECTLY OR INDIRECTLY BY EXTRACTION FROM SUBSTANCES OF NATURAL ORIGIN, OR INDEPENDENTLY BY MEANS OF CHEMICAL SYNTHESIS, OR BY A COMBINATION OF EXTRACTION AND CHEMICAL SYNTHESIS; OR

(II) THE PACKAGING, REPACKAGING, LABELING, RELABELING, OR DISTRIBUTION OF PRESCRIPTION DRUG PRODUCTS.

(B) (1) THE SECRETARY MAY NEGOTIATE DISCOUNT PRICES OR REBATES FOR PRESCRIPTION DRUGS FROM DRUG MANUFACTURERS AND LABELERS.

(2) A DRUG MANUFACTURER OR LABELER THAT SELLS PRESCRIPTION DRUGS IN THIS STATE MAY VOLUNTARILY ELECT TO NEGOTIATE:

(I) SUPPLEMENTAL REBATES FOR THE MARYLAND MEDICAL ASSISTANCE PROGRAM OVER AND ABOVE THOSE REQUIRED BY 42 U.S.C. § 1396R-8; AND

(II) DISCOUNT PRICES AND REBATES FOR ANY OTHER STATE PROGRAMS THAT PAY FOR OR ACQUIRE PRESCRIPTION DRUGS.

(C) WHEN NEGOTIATING REBATE TERMS, THE SECRETARY SHALL CONSIDER THE FOLLOWING:

(1) THE REBATE CALCULATED UNDER THE MEDICAID REBATE PROGRAM UNDER 42 U.S.C. § 1396R-8;

(2) THE PRICE PROVIDED TO ELIGIBLE ENTITIES UNDER 42 U.S.C. § 256B; AND

(3) ANY OTHER AVAILABLE INFORMATION ON PRESCRIPTION DRUG PRICES, DISCOUNTS, AND REBATES.

(D) (1) THE SECRETARY MAY REVIEW WHETHER TO PLACE A MANUFACTURER'S OR LABELER'S PRODUCTS ON THE PRIOR AUTHORIZATION LIST FOR THE MARYLAND MEDICAL ASSISTANCE PROGRAM AND TAKE SIMILAR ACTIONS INVOLVING FORMULARIES FOR ANY OTHER STATE-AUTHORIZED PRESCRIPTION DRUG PROGRAM, IF THE SECRETARY AND A DRUG MANUFACTURER OR LABELER FAIL TO REACH AN AGREEMENT ON THE TERMS OF A SUPPLEMENTAL REBATE OR A DISCOUNT.

(2) A PROGRAM FOR PRIOR AUTHORIZATION MUST MEET THE REQUIREMENTS OF 42 U.S.C. § 1396R-8.

(E) THE DEPARTMENT SHALL RELEASE THE NAMES OF MANUFACTURERS AND LABELERS THAT DO NOT ENTER INTO A REBATE AGREEMENT AND DISTRIBUTE THIS INFORMATION TO DOCTORS, PHARMACISTS, AND OTHER HEALTH CARE PROFESSIONALS.

(F) THE SECRETARY SHALL PROMULGATE REGULATIONS TO CARRY OUT THE PROVISIONS OF THIS SECTION.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2002.