SENATE BILL 623

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By: **Senators Hoffman ~~and Bromwell~~, Astle, Bromwell, DeGrange, Della, Exum, Frosh, Hafer, Hooper, Kelley, Middleton, Roesser, Teitelbaum, Van Hollen, Ruben, Lawlah, and Currie**
Introduced and read first time: February 1, 2002
Assigned to: Budget and Taxation and Finance

Committee Report: Favorable with amendments
Senate action: Adopted with floor amendments
Read second time: March 31, 2002

CHAPTER_____

AN ACT concerning

Prescription Drug Manufacturer Rebates - ~~Supplementary Appropriation - Medical Care Programs Administration~~ State Funded Prescription Drug Programs

FOR the purpose of requiring the Department of Health and Mental Hygiene to establish a State prescription drug spending control program that may include certain preferred drug ~~formularies~~ lists and ~~is required to include~~ a certain process for managing drug therapies; authorizing the Department to establish a preferred drug ~~formulary~~ list~~,~~ and to negotiate certain supplemental rebates~~,~~ ; ~~and to enter into certain agreements with manufacturers of generic drugs; providing that certain rebates may be less than a certain amount under certain circumstances;~~ establishing a State Pharmaceutical and Therapeutics Committee within the Department for the purpose of developing a preferred drug ~~formulary~~ list; ~~providing that an agreement to pay a certain supplemental rebate will guarantee certain consideration by the Committee;~~ specifying the membership, terms, officers, quorum, required meetings, and duties of the Committee; authorizing the Secretary of Health and Mental Hygiene to remove a member of the Committee for good cause; providing that to the extent feasible, the Committee is required to perform a certain review and may make certain recommendations; requiring the Department to provide staff for the Committee, to provide a certain notice, and to ensure that certain drugs are reviewed at a certain meeting of the Committee; requiring the Department to ensure a certain product review by the Committee under certain circumstances; requiring the Department to make certain preferred drug list decisions based on certain criteria; authorizing the Department to establish prior authorization requirements for certain drugs and drug classes under certain circumstances;

prohibiting the Department from establishing prior authorization for certain medications; requiring the Department to inform the Committee of certain decisions, to publish a certain preferred drug ~~formulary, to~~ list, ~~provide certain notice of changes in a certain preferred drug formulary,~~ and to establish ~~a~~ certain appeals ~~process~~ processes; ~~requiring the Department to develop and implement a certain drug benefit management program;~~ authorizing the Department to seek federal waivers, amendments to the State Medical Assistance Program plan, or adopt regulations; requiring the Department to make a certain annual report by a certain date; requiring any funds received by the Department as the result of supplemental rebates paid by certain manufacturers to be distributed to a certain fund; creating the Maryland Medical Assistance Prescription Drugs Fund; specifying the purpose and uses of the Fund and that the Fund is a special, nonlapsing fund that is not subject to certain provisions of law; specifying that the Fund may only be used to provide funds to the Medical Care Programs Administration in the Department to offset the cost of prescription drugs in certain programs; requiring the Department to establish certain regulations for certain copayments; ~~requiring the Department of Budget and Management to establish a certain preferred drug formulary and a certain drug benefits management program;~~ requiring the Department of Budget and Management to ~~attempt to negotiate certain agreements with manufacturers of prescription drugs~~ establish a preferred drug list, to negotiate certain supplemental rebates, to establish certain prior authorization requirements for prescription drugs, to inform a certain committee of certain decisions, to publish a certain preferred drug ~~formulary~~ list, to establish ~~a~~ certain appeals ~~process~~ processes, ~~to contract with a private entity for certain duties,~~ and to make a certain report by a certain date; prohibiting the Department from establishing prior authorization for certain medications; defining certain terms; ~~providing for the legislative appropriation for a certain fiscal year of certain revenues derived as a result of this Act;~~ requiring the Department of Health and Mental Hygiene to report to certain committees of the General Assembly at a certain time; and generally relating to prescription drug manufacturer rebates ~~and a supplementary appropriation for a certain fiscal year for the Medical Care Programs Administration~~ and State funded prescription drug programs.

BY repealing and reenacting, with amendments,
Article - Health - General
Section 15-118
Annotated Code of Maryland
(2000 Replacement Volume and 2001 Supplement)

BY adding to
Article - Health - General
Section 15-118.1
Annotated Code of Maryland
(2000 Replacement Volume and 2001 Supplement)

BY repealing and reenacting, with amendments,
Article - Health - General
Section 15-124(b)
Annotated Code of Maryland
(2000 Replacement Volume and 2001 Supplement)

BY adding to
Article - State Personnel and Pensions
Section 2-503(e)
Annotated Code of Maryland
(1997 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

15-118.

(a) (1) Unless the prescriber directs otherwise on the form or on an attached signed certification of need, the generic form of the drug authorized under § 12-504 of the Health Occupations Article shall be used to fill the prescription.

(2) If the appropriate generic drug is not generally available, the Department may waive the requirement for generic substitution under paragraph (1) of this subsection.

(b) (1) Except as provided under paragraph (2) of this subsection, the Program shall establish maximum reimbursement levels for the drug products for which there is a generic equivalent authorized under § 12-504 of the Health Occupations Article, based on the cost of the generic product.

(2) If a prescriber directs a specific brand name drug, the reimbursement level shall be based on the cost of the brand name product.

(c) (1) Except as provided under paragraph (4) of this subsection and unless the change is made by an emergency regulation, the Program shall notify all pharmacies under contract with the Program in writing of changes in the Pharmaceutical Benefit Program rules or requirements at least 30 days before the change is effective.

(2) Changes that require 30 days' advance written notice under paragraph (1) of this subsection are:

(i) Exclusion of coverage for classes of drugs as specified by contract;

(ii) Changes in prior or preauthorization procedures; [and]

(iii) CHANGES ~~IN~~ TO THE PREFERRED DRUG ~~FORMULARY~~ LIST ESTABLISHED UNDER § 15-118.1 OF THIS SUBTITLE; AND

(IV) Selection of new prescription claims processors.

(3) If the Program fails to provide advance notice as required under paragraph (1) of this subsection, it shall honor and pay in full any claim under the Program rules or requirements that existed before the change for 30 days after the postmarked date of the notice.

(4) Notwithstanding any other provision of law, the notice requirements of this subsection do not apply to the addition of new generic drugs authorized under § 12-504 of the Health Occupations Article.

(d) The Secretary shall adopt regulations to carry out the provisions of this section.

15-118.1.

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

(2) "AUTHORIZED PRESCRIBER" MEANS A LICENSED PHYSICIAN OR CERTIFIED NURSE PRACTITIONER TO THE EXTENT PERMITTED UNDER § 8-508 OF THE HEALTH OCCUPATIONS ARTICLE, OR OTHER INDIVIDUAL AUTHORIZED BY LAW TO PRESCRIBE PRESCRIPTION OR NONPRESCRIPTION DRUGS.

~~(2)~~ (3) "COMMITTEE" MEANS THE STATE PHARMACEUTICAL AND THERAPEUTICS COMMITTEE ESTABLISHED UNDER SUBSECTION (F) OF THIS SECTION.

~~(3)~~ (4) (I) "MANUFACTURER" MEANS A MANUFACTURER OF PRESCRIPTION DRUGS AS DEFINED IN 42 U.S.C. § 1396R-8 (K)(5).

(II) "MANUFACTURER" INCLUDES A SUBSIDIARY OR AFFILIATE OF A MANUFACTURER.

~~(4)~~ (5) "MARYLAND PHARMACY ASSISTANCE PROGRAM" OR "MPAP" MEANS THE MARYLAND PHARMACY ASSISTANCE PROGRAM ESTABLISHED UNDER § 15-124 OF THIS SUBTITLE.

~~(5)~~ (6) "PARTICIPATING RETAIL PHARMACY" MEANS A RETAIL PHARMACY OR OTHER PERSON LICENSED OR OTHERWISE PERMITTED BY LAW TO DISPENSE PRESCRIPTION DRUGS IN THE STATE THAT PARTICIPATES IN THE PROGRAM.

~~(6)~~ (7) "STATE PRESCRIPTION DRUG PROGRAM" MEANS THE PRESCRIPTION DRUG BENEFITS PROGRAM FOR STATE EMPLOYEES IN THE STATE EMPLOYEE AND RETIREE HEALTH AND WELFARE BENEFITS PROGRAM DEVELOPED

AND ADMINISTERED BY THE SECRETARY OF BUDGET AND MANAGEMENT UNDER TITLE 2, SUBTITLE 5 OF THE STATE PERSONNEL AND PENSIONS ARTICLE.

(B) THIS SECTION DOES NOT APPLY TO PROGRAM RECIPIENTS ENROLLED IN MANAGED CARE ORGANIZATIONS UNDER § 15-103 OF THIS SUBTITLE.

~~(B)~~ (C) THE DEPARTMENT, IN CONSULTATION WITH THE DEPARTMENT OF BUDGET AND MANAGEMENT, SHALL ESTABLISH A PRESCRIPTION DRUG SPENDING CONTROL PROGRAM WITHIN THE PROGRAM, MPAP, AND THE STATE PRESCRIPTION DRUG PROGRAM THAT~~:~~

~~(1)~~ MAY INCLUDE:

(1) A PREFERRED DRUG ~~FORMULARY~~ LIST IN ACCORDANCE WITH THIS SECTION; AND

(2) ~~ESTABLISHES~~ A PROCESS FOR MANAGING THE DRUG THERAPIES OF PROGRAM RECIPIENTS AND MPAP PARTICIPANTS WHO ARE USING A SIGNIFICANT NUMBER OF PRESCRIPTION DRUGS EACH MONTH.

~~(C)~~ ~~(1)~~ (D) THE DEPARTMENT MAY ESTABLISH A PREFERRED DRUG ~~FORMULARY~~ LIST FOR THE PROGRAM AND MPAP IN ACCORDANCE WITH THE PROVISIONS OF 42 U.S.C. § 1396R-8, AND THIS SECTION AND MAY NEGOTIATE SUPPLEMENTAL REBATES FROM MANUFACTURERS FOR THE PROGRAM AND MPAP ~~THAT ARE NO LESS THAN 10% OF THE AVERAGE MANUFACTURER PRICE AS DEFINED IN 42 U.S.C. § 1936 ON THE LAST DAY OF A QUARTER.~~

~~(2) (I) THE DEPARTMENT MAY ENTER INTO AGREEMENTS THAT REQUIRE MANUFACTURERS OF GENERIC DRUGS PRESCRIBED TO PROGRAM RECIPIENTS AND MPAP PARTICIPANTS TO PROVIDE REBATES OF AT LEAST 15.1% OF THE AVERAGE MANUFACTURER PRICE FOR THE MANUFACTURER'S GENERIC PRODUCTS.~~

~~(II) THE ARRANGEMENTS ESTABLISHED UNDER SUBPARAGRAPH (I) OF THIS PARAGRAPH SHALL REQUIRE THAT IF A GENERIC DRUG MANUFACTURER PAYS FEDERAL REBATES FOR MEDICAID-REIMBURSED DRUGS AT A LEVEL BELOW 15.1%, THE MANUFACTURER SHALL PROVIDE A SUPPLEMENTAL REBATE TO THE STATE IN AN AMOUNT NECESSARY TO ACHIEVE A 15.1% REBATE LEVEL.~~

~~(3) THE SUPPLEMENTAL REBATES AUTHORIZED IN PARAGRAPH (1) OF THIS SUBSECTION MAY BE IN AN AMOUNT LESS THAN 10% OF THE AVERAGE MANUFACTURER PRICE AS DEFINED IN 42 U.S.C. § 1936 ON THE LAST DAY OF A QUARTER IF:~~

~~(I) THE REBATE REQUIRED BY TITLE XIX OF THE SOCIAL SECURITY ACT EXCEEDS 25%;~~

~~(II) THE SUPPLEMENTAL REBATE UNDER PARAGRAPH (1) OF THIS SUBSECTION EXCEEDS 25%; OR~~

~~(III) THE ADDITION OF THE REBATES IN ITEMS (I) AND (II) OF THIS PARAGRAPH EXCEEDS 25%.~~

~~(4) THERE IS NO UPPER LIMIT ON THE SUPPLEMENTAL REBATES THE DEPARTMENT MAY NEGOTIATE UNDER THIS SECTION.~~

~~(5) THE DEPARTMENT MAY DETERMINE THAT SPECIFIC DRUG PRODUCTS, BRAND NAME DRUGS, OR GENERIC DRUGS, ARE COMPETITIVE AT LOWER REBATE PERCENTAGES THAN THE PERCENTAGE REQUIRED IN PARAGRAPH (1) OF THIS SUBSECTION.~~

~~(6) (I) AN AGREEMENT TO PAY THE SUPPLEMENTAL REBATE PERCENTAGE NEGOTIATED BY THE DEPARTMENT UNDER THIS SUBSECTION WILL GUARANTEE A MANUFACTURER THAT THE COMMITTEE WILL CONSIDER A PRODUCT FOR INCLUSION ON THE PREFERRED DRUG FORMULARY.~~

~~(II) NOTWITHSTANDING THE PROVISIONS OF THIS SUBSECTION, A MANUFACTURER IS NOT GUARANTEED PLACEMENT ON THE FORMULARY BECAUSE THE MANUFACTURER HAS PAID THE MINIMUM SUPPLEMENTAL REBATE.~~

~~(7) THE DEPARTMENT SHALL MAKE FORMULARY DECISIONS BASED ON THE CLINICAL EFFICACY OF A DRUG, THE RECOMMENDATIONS OF THE COMMITTEE, AND THE PRICE OF COMPETING PRODUCTS MINUS FEDERAL AND STATE REBATES~~.

~~(D)~~ (E) THE DEPARTMENT MAY CONTRACT WITH A PERSON TO CONDUCT NEGOTIATIONS FOR SUPPLEMENTAL REBATES AUTHORIZED UNDER SUBSECTION ~~(C)~~ (D) OF THIS SECTION.

~~(E)~~ (F) THE DEPARTMENT~~, AT ITS OWN DISCRETION, MAY ELECT TO RECEIVE~~ MAY IMPLEMENT OTHER PROGRAM BENEFITS ~~THAT OFFSET A~~ TO OFFSET MEDICAID OR MPAP ~~EXPENDITURE~~ EXPENDITURES IN LIEU OF, OR IN ADDITION TO, A SUPPLEMENTAL REBATE UNDER SUBSECTION ~~(C)~~ (D) OF THIS SECTION INCLUDING:

(1) ~~DISEASE MANAGEMENT PROGRAMS;~~ INTENSIFIED BENEFITS MANAGEMENT PROGRAMS FOR:

(I) NEW PROGRAM AND MPAP ENROLLEES;

(II) HIGH COST DRUG UTILIZERS; AND

(III) RESIDENTS OF LONG-TERM CARE FACILITIES;

(2) DRUG PRODUCT DONATION PROGRAMS;

(3) DRUG UTILIZATION CONTROL PROGRAMS;

(4) PRESCRIBER, PROGRAM RECIPIENT, AND MPAP PARTICIPANT~~;~~ ~~COUNSELING AND EDUCATION, FRAUD AND ABUSE INITIATIVES; OR~~

(I) COUNSELING;

(II) EDUCATION WITH AN EMPHASIS ON COST-EFFECTIVE DRUG THERAPIES; AND

(III) FRAUD AND ABUSE INITIATIVES; AND

(5) OTHER SERVICES OR ADMINISTRATIVE PROGRAMS ~~WITH GUARANTEED SAVINGS TO THE PROGRAM OR MPAP IN THE FISCAL YEAR IN WHICH THE SUPPLEMENTAL REBATE WOULD HAVE BEEN APPLICABLE~~ TO REDUCE PROGRAM OR MPAP EXPENDITURES, INCLUDING:

(I) THE USE OF DIFFERENTIAL COPAYS AND DISPENSING FEES;

(II) IMPLEMENTATION OF A 34-DAY LIMIT ON PRESCRIPTION DRUGS; AND

(III) PHARMACY INCENTIVE PROGRAMS TO ENCOURAGE THE USE OF GENERIC AND LOWER COST BRAND NAME DRUGS.

~~(F)~~ (G) (1) THERE IS A STATE PHARMACEUTICAL AND THERAPEUTICS COMMITTEE WITHIN THE DEPARTMENT FOR THE PURPOSE OF DEVELOPING A PREFERRED DRUG ~~FORMULARY~~ LIST UNDER 42 U.S.C. § 1396R-8 AND THIS SECTION.

(2) THE COMMITTEE CONSISTS OF THE FOLLOWING ~~11~~ 13 MEMBERS APPOINTED BY THE GOVERNOR AND CONSISTENT WITH THE REQUIREMENTS OF 42 U.S.C. § 1396R-8:

(I) FIVE MEMBERS SHALL BE LICENSED MARYLAND PHYSICIANS IN THE STATE;

(II) FIVE MEMBERS SHALL BE LICENSED MARYLAND PHARMACISTS IN THE STATE; AND

(III) ~~ONE MEMBER SHALL BE A~~ THREE MEMBERS SHALL BE CONSUMER ~~REPRESENTATIVE~~ REPRESENTATIVES DOMICILED IN THE STATE.

(3) IN APPOINTING THE MEMBERS TO THE COMMITTEE, THE GOVERNOR SHALL MAKE BEST EFFORTS TO ENSURE REPRESENTATION OF:

(I) LICENSED MARYLAND PHYSICIANS THAT PARTICIPATE IN THE PROGRAM;

(II) LICENSED MARYLAND PHARMACISTS EMPLOYED BY PARTICIPATING RETAIL PHARMACIES; AND

(III) LICENSED MARYLAND PHYSICIANS OR LICENSED MARYLAND PHARMACISTS WITH EXPERIENCE IN DEVELOPING OR PRACTICING UNDER A PREFERRED DRUG ~~FORMULARY~~ LIST.

(4) (I) THE TERM OF A MEMBER IS 3 YEARS.

(II) A MEMBER MAY NOT BE APPOINTED FOR MORE THAN TWO CONSECUTIVE FULL TERMS.

(III) AT THE END OF A TERM, A MEMBER CONTINUES TO SERVE UNTIL A SUCCESSOR IS APPOINTED.

(IV) THE SECRETARY MAY REMOVE ANY MEMBER OF THE COMMITTEE FOR GOOD CAUSE.

(5) A MEMBER OF THE COMMITTEE MAY NOT RECEIVE COMPENSATION FOR SERVING ON THE COMMITTEE, BUT IS ENTITLED TO REIMBURSEMENT FOR EXPENSES UNDER THE STANDARD STATE TRAVEL REGULATIONS, AS PROVIDED IN THE STATE.

(6) THE MEMBERS OF THE COMMITTEE SHALL ANNUALLY ELECT A CHAIRMAN FROM THE MEMBERSHIP OF THE COMMITTEE.

(7) A QUORUM OF THE COMMITTEE SHALL BE A MAJORITY OF THE APPOINTED MEMBERSHIP OF THE COMMITTEE.

(8) THE COMMITTEE SHALL MEET NOT LESS THAN EVERY 3 MONTHS AND MAY MEET AT OTHER TIMES AT THE DISCRETION OF THE CHAIRMAN AND MEMBERS.

(9) THE COMMITTEE:

(I) SHALL DEVELOP RECOMMENDATIONS FOR A PREFERRED DRUG ~~FORMULARY~~ LIST FOR THE PROGRAM AND MPAP BY CONSIDERING THE ~~CLINICAL EFFICACY, SAFETY, AND COST EFFECTIVENESS OF A PRODUCT;~~:

1. CLINICAL EVIDENCE FOUND IN LABELING, DRUG COMPENDIA, AND PEER REVIEWED CLINICAL LITERATURE PERTAINING TO THE USE OF THE DRUG IN THE RELEVANT POPULATION; AND

2. COST-EFFECTIVENESS OF THE PRODUCT;

(II) MAY MAKE RECOMMENDATIONS TO THE DEPARTMENT REGARDING THE PRIOR AUTHORIZATION OF ANY PRESCRIBED DRUG COVERED BY THE PROGRAM AND MPAP;

(III) SHALL ENSURE THAT MANUFACTURERS THAT HAVE AGREED TO PROVIDE A SUPPLEMENTAL REBATE TO THE PROGRAM AND MPAP UNDER SUBSECTION ~~(C)~~ (D) OF THIS SECTION ARE PROVIDED WITH THE OPPORTUNITY TO PRESENT EVIDENCE SUPPORTING INCLUSION OF A PRODUCT ON THE PREFERRED DRUG ~~FORMULARY~~ LIST; AND

(IV) IN CONSULTATION WITH THE DEPARTMENT OF BUDGET AND MANAGEMENT, SHALL:

1. REVIEW WHETHER THE STATE IS RECEIVING AN APPROPRIATE LEVEL OF REBATES IN THE STATE PRESCRIPTION DRUG PROGRAM;

2. MAKE RECOMMENDATIONS ON MECHANISMS TO MAXIMIZE PRESCRIPTION DRUG COST SAVINGS IN THE STATE PRESCRIPTION DRUG PROGRAM INCLUDING A DRUG BENEFIT MANAGEMENT PROGRAM TO MANAGE THE DRUG THERAPIES OF STATE PRESCRIPTION DRUG PROGRAM ENROLLEES WHO ARE USING A SIGNIFICANT NUMBER OF PRESCRIPTION DRUGS EACH MONTH;

3. DEVELOP A PREFERRED DRUG ~~FORMULARY~~ LIST FOR THE STATE PRESCRIPTION DRUG PROGRAM BY CONSIDERING THE ~~CLINICAL EFFICACY, SAFETY, AND COST-EFFECTIVENESS OF A PRODUCT; AND~~:

A. CLINICAL EVIDENCE FOUND IN LABELING, DRUG COMPENDIA, AND PEER REVIEWED CLINICAL LITERATURE PERTAINING TO THE USE OF THE DRUG IN THE RELEVANT POPULATION; AND

B. COST-EFFECTIVENESS OF THE PRODUCT; AND

4. MAKE RECOMMENDATIONS TO THE DEPARTMENT OF BUDGET AND MANAGEMENT REGARDING THE PRIOR AUTHORIZATION OF ANY PRESCRIBED DRUG COVERED BY THE STATE PRESCRIPTION DRUG PROGRAM.

(10) TO THE EXTENT FEASIBLE, THE COMMITTEE:

(I) SHALL REVIEW ALL DRUG CLASSES INCLUDED IN THE PROGRAM, MPAP, AND STATE PRESCRIPTION DRUG PROGRAM PREFERRED DRUG ~~FORMULARIES~~ LISTS AT LEAST EVERY 12 MONTHS; AND

(II) MAY RECOMMEND ADDITIONS TO AND DELETIONS FROM THE PROGRAM, MPAP, AND STATE PRESCRIPTION DRUG PROGRAM PREFERRED DRUG ~~FORMULARIES~~ LISTS TO ENSURE THAT EACH ~~FORMULARY~~ LIST PROVIDES MEDICALLY APPROPRIATE DRUG THERAPIES WHILE PROVIDING COST SAVINGS.

(11) THE DEPARTMENT SHALL PROVIDE STAFF SUPPORT FOR THE COMMITTEE.

~~(G)~~ (H) (1) THE DEPARTMENT SHALL PROVIDE TIMELY NOTICE AND ENSURE THAT ANY DRUG THAT HAS BEEN APPROVED OR HAD ANY OF ITS PARTICULAR USES APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION UNDER A PRIORITY REVIEW CLASSIFICATION WILL BE REVIEWED BY THE COMMITTEE AT THE NEXT REGULARLY SCHEDULED MEETING.

(2) TO THE EXTENT POSSIBLE, UPON NOTICE BY A MANUFACTURER, THE DEPARTMENT SHALL ENSURE THAT A PRODUCT REVIEW BY THE COMMITTEE FOR ANY NEW PRODUCT WILL OCCUR AT THE NEXT REGULARLY SCHEDULED COMMITTEE MEETING.

(I) (1) THE DEPARTMENT SHALL MAKE PREFERRED DRUG LIST DECISIONS BASED ON:

(I) THE CLINICAL EFFICACY OF A DRUG;

(II) THE RECOMMENDATIONS OF THE COMMITTEE; AND

(III) THE PRICE OF COMPETING PRODUCTS MINUS FEDERAL AND STATE REBATES.

(2) THE PREFERRED DRUG LIST DEVELOPED BY THE DEPARTMENT SHALL:

(I) PROVIDE FOR COVERAGE OF DRUGS IN EVERY THERAPEUTIC CLASS; AND

(II) OFFER A CHOICE OF PHARMACEUTICALS OR BIOLOGICAL ENTITIES WITHOUT AN ADMINISTRATIVE PREFERENCE FOR EACH THERAPEUTIC CLASS IN WHICH THERE ARE TWO OR MORE PHARMACEUTICAL OR BIOLOGICAL ENTITIES APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION.

~~(II)~~ (J) (1) SUBJECT TO THE PROVISIONS OF PARAGRAPHS (2) ~~AND (3)~~, (3), (4), AND (5) OF THIS SUBSECTION, THE DEPARTMENT MAY ESTABLISH PRIOR AUTHORIZATION REQUIREMENTS FOR:

(I) PRESCRIPTION DRUGS NOT LISTED ON THE PREFERRED DRUG ~~FORMULARY~~ LIST ESTABLISHED UNDER THIS SECTION;

(II) PRESCRIPTION DRUGS FOR SPECIFIC POPULATIONS OF PROGRAM RECIPIENTS AND MPAP PARTICIPANTS REGARDLESS OF WHETHER THE DRUGS ARE LISTED ON THE PREFERRED DRUG ~~FORMULARY~~ LIST; AND

(III) SPECIFIC DRUG CLASSES OR SPECIFIC DRUGS REGARDLESS OF WHETHER THE DRUG CLASSES OR DRUGS ARE LISTED ON THE PREFERRED DRUG ~~FORMULARY~~ LIST TO PREVENT FRAUD, ABUSE, OVERUSE, AND POSSIBLE DANGEROUS DRUG INTERACTIONS.

(2) THE DEPARTMENT MAY NOT ESTABLISH PRIOR AUTHORIZATION REQUIREMENTS OR RESTRICT COVERAGE FOR MEDICATIONS USED TO TREAT:

(I) MENTAL ILLNESSES AND BRAIN DISORDERS, INCLUDING ATYPICAL ANTIPSYCHOTIC MEDICATIONS, CONVENTIONAL ANTIPSYCHOTIC MEDICATIONS, ~~AND~~ ACTIVE SEROTONIN RE-UPTAKE INHIBITORS, ATYPICAL ANTIDEPRESSANTS, AND DRUGS TO TREAT EPILEPSY AND OTHER CENTRAL NERVOUS SYSTEM BRAIN DISORDERS; AND

(II) THE HUMAN IMMUNODEFICIENCY VIRUS (HIV) OR THE ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS).

~~(2)~~ (3) FOR ANY PRESCRIPTION DRUG SUBJECT TO PRIOR AUTHORIZATION, THE DEPARTMENT SHALL IMPLEMENT PROCEDURES TO ENSURE THAT:

(I) THE DEPARTMENT RESPONDS TO A REQUEST FROM AN AUTHORIZED PRESCRIBER FOR PRIOR ~~CONSULTATION~~ AUTHORIZATION BY TELEPHONE OR OTHER TELECOMMUNICATION DEVICE WITHIN 24 HOURS AFTER RECEIPT OF A REQUEST FOR PRIOR ~~CONSULTATION~~ AUTHORIZATION; ~~AND~~

(II) A 72-HOUR SUPPLY OF THE PRESCRIBED DRUG WILL BE PROVIDED IN AN EMERGENCY OR WHEN THE DEPARTMENT DOES NOT PROVIDE A RESPONSE WITHIN 24 HOURS; ~~AND~~

(III) FOR A SINGLE SOURCE COVERED OUTPATIENT DRUG THAT IS NEWLY APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION, THE DRUG IS INCLUDED ON THE PREFERRED DRUG LIST FOR A PERIOD OF 6 MONTHS UNLESS THE DEPARTMENT, WITH THE RECOMMENDATION OF THE COMMITTEE, DETERMINES THAT THE DRUG SHOULD BE EXCLUDED FROM THE PREFERRED DRUG LIST; AND

(IV) ALL REQUESTS FOR PRIOR AUTHORIZATION ARE APPROVED BY AN AUTHORIZED PRESCRIBER WITHIN THE DEPARTMENT.

(4) (I) THE DEPARTMENT SHALL ESTABLISH AN APPEALS PROCESS FOR A PROGRAM RECIPIENT, A MPAP PARTICIPANT, OR AN AUTHORIZED PRESCRIBER TO APPEAL AN ADVERSE DECISION BY THE DEPARTMENT REGARDING PRIOR AUTHORIZATION TO A LICENSED PHYSICIAN.

(II) THE DEPARTMENT SHALL ENSURE THAT A PROGRAM RECIPIENT, A MPAP PARTICIPANT, OR AN AUTHORIZED PRESCRIBER RECEIVES A RESPONSE TO AN APPEAL WITHIN 48 HOURS.

(5) THE DEPARTMENT SHALL ENSURE THAT THE PRIOR AUTHORIZATION FOR A PRESCRIPTION DRUG IS VALID FOR AT LEAST A 1-YEAR PERIOD IF AN INDIVIDUAL HAS RECEIVED PRIOR AUTHORIZATION FOR:

(I) A PRESCRIPTION DRUG TO TREAT A CHRONIC CONDITION; OR

(II) CONTRACEPTIVE DRUGS AND ITEMS.

~~(I)~~ (K) THE DEPARTMENT SHALL:

(1) INFORM THE COMMITTEE OF ANY DECISIONS REGARDING PRESCRIPTION DRUGS SUBJECT TO PRIOR AUTHORIZATION; AND

(2) ~~PUBLISH AND DISSEMINATE THE PREFERRED DRUG FORMULARY TO ALL MEDICAID PROVIDERS, MPAP PROVIDERS, AND PARTICIPATING RETAIL PHARMACIES IN THE STATE; AND~~ ANNUALLY PUBLISH THE PREFERRED DRUG LIST IN THE MARYLAND REGISTER AND MAINTAIN AN UPDATED VERSION OF THE PREFERRED DRUG LIST ON THE DEPARTMENT'S INTERNET WEBSITE.

~~(3) ESTABLISH AN APPEALS PROCESS FOR A PROGRAM RECIPIENT OR MPAP PARTICIPANT TO APPEAL A PREFERRED DRUG FORMULARY DECISION BY THE DEPARTMENT.~~

~~(J) (1) THE DEPARTMENT SHALL DEVELOP AND IMPLEMENT A DRUG BENEFIT MANAGEMENT PROGRAM TO MANAGE THE DRUG THERAPIES OF PROGRAM RECIPIENTS AND MPAP PARTICIPANTS WHO ARE USING A SIGNIFICANT NUMBER OF PRESCRIPTION DRUGS EACH MONTH.~~

~~(2) THE MANAGEMENT PROCESS MAY INCLUDE COMPREHENSIVE, PHYSICIAN-DIRECTED MEDICAL-RECORD REVIEWS, CLAIMS ANALYSES, AND CASE EVALUATIONS TO DETERMINE THE MEDICAL NECESSITY AND APPROPRIATENESS OF A PATIENT'S TREATMENT PLAN AND DRUG THERAPIES.~~

~~(3) THE DEPARTMENT MAY CONTRACT WITH A PRIVATE ORGANIZATION TO PROVIDE SERVICES FOR A DRUG BENEFIT MANAGEMENT PROGRAM.~~

~~(4) THE DRUG BENEFIT MANAGEMENT PROGRAM SHALL INCLUDE INITIATIVES TO MANAGE DRUG THERAPIES FOR HIV/AIDS PATIENTS, PATIENTS USING 20 OR MORE UNIQUE PRESCRIPTIONS IN A 180-DAY PERIOD, AND THE TOP 1,000 PATIENTS IN ANNUAL SPENDING.~~

~~(K)~~ (L) THE DEPARTMENT MAY:

(1) SEEK ANY FEDERAL WAIVERS OR PROGRAM PLAN AMENDMENTS NECESSARY TO IMPLEMENT THE PROVISIONS OF THIS SECTION; AND

(2) ADOPT REGULATIONS TO CARRY OUT THE PROVISIONS OF THIS SECTION.

~~(L)~~ (M) ON OR BEFORE DECEMBER 1 OF EACH YEAR, THE DEPARTMENT SHALL REPORT TO THE GENERAL ASSEMBLY, IN ACCORDANCE WITH § 2-1246 OF THE STATE GOVERNMENT ARTICLE, ON THE AMOUNT OF SUPPLEMENTAL REBATES OR OTHER COST CONTAINMENT MEASURES UNDER THIS SECTION AND THEIR EFFECT ON PRESCRIPTION DRUG EXPENDITURES IN THE PROGRAM AND MPAP.

(N) NOTWITHSTANDING ANY OTHER PROVISION OF LAW, ANY FUNDS RECEIVED BY THE DEPARTMENT AS THE RESULT OF SUPPLEMENTAL REBATES PAID BY MANUFACTURERS IN THE PROGRAM OR MPAP SHALL BE DISTRIBUTED TO THE MARYLAND MEDICAL ASSISTANCE PRESCRIPTION DRUGS FUND CREATED UNDER SUBSECTION (O) OF THIS SECTION.

(O) (1) IN THIS SUBSECTION, "FUND" MEANS THE MARYLAND MEDICAL ASSISTANCE PRESCRIPTION DRUGS FUND.

(2) THERE IS A MARYLAND MEDICAL ASSISTANCE PRESCRIPTION DRUGS FUND.

(3) THE PURPOSE OF THE FUND IS TO PROVIDE FUNDS TO THE MEDICAL CARE PROGRAMS ADMINISTRATION IN THE DEPARTMENT TO OFFSET THE COST OF PRESCRIPTION DRUGS AND THE COST OF PHARMACY REIMBURSEMENT IN THE PROGRAM AND MPAP.

(4) THE SECRETARY SHALL ADMINISTER THE FUND.

(5) (I) THE FUND IS A SPECIAL, NONLAPSING FUND THAT IS NOT SUBJECT TO § 7-302 OF THE STATE FINANCE AND PROCUREMENT ARTICLE.

(II) THE TREASURER SHALL HOLD THE FUND SEPARATELY AND THE COMPTROLLER SHALL ACCOUNT FOR THE FUND.

(6) THE FUND CONSISTS OF ANY FUNDS RECEIVED BY THE DEPARTMENT AS THE RESULT OF SUPPLEMENTAL REBATES PAID BY MANUFACTURERS IN THE PROGRAM OR MPAP.

(7) ANY INTEREST OR OTHER INVESTMENT EARNINGS OF THE FUND SHALL BE CREDITED AND PAID INTO THE FUND.

(8) THE FUND MAY BE USED ONLY TO PROVIDE FUNDS TO THE MEDICAL CARE PROGRAMS ADMINISTRATION IN THE DEPARTMENT TO OFFSET THE COSTS OF PRESCRIPTION DRUGS AND PHARMACY REIMBURSEMENT IN THE PROGRAM AND MPAP.

(9) THE TREASURER SHALL INVEST THE MONEY OF THE FUND IN THE SAME MANNER AS ANY OTHER STATE MONEY MAY BE INVESTED.

(10) EXPENDITURES FROM THE FUND MAY BE MADE ONLY IN ACCORDANCE WITH THE STATE BUDGET.

15-124.

(b) (1) (i) Reimbursement under the Maryland Pharmacy Assistance Program [shall] MAY be limited to maintenance drugs, anti-infectives, and AZT as specified in regulations to be issued by the Secretary after consultation with the Maryland Pharmacists Association.

(ii) 1. For any drug on the Program's interchangeable drug list, the Program shall reimburse providers in an amount not more than it would reimburse for the drug's generic equivalent, unless the individual's physician states, in his or her own handwriting, on the face of the prescription, that a specific brand is "medically necessary" for the particular patient.

2. If an appropriate generic drug is not generally available, the Department may waive the reimbursement requirement under sub-subparagraph 1 of this subparagraph.

(2) (I) The reimbursement shall be up to the amount paid for the same items or services under the pharmacy program of the Maryland Medical Assistance Program and shall be subject to a copayment [of not more than $5.00 for each covered item or service] AS ESTABLISHED BY THE DEPARTMENT IN REGULATION.

(II) IN ESTABLISHING A COPAYMENT, THE DEPARTMENT MAY ESTABLISH A SYSTEM OF TIERED COPAYMENTS, INCLUDING DIFFERENT COPAYMENTS FOR DIFFERENT CLASSES OF DRUGS, OR OTHER DIFFERENTIAL COPAYMENTS.

Article - State Personnel and Pensions

2-503.

(E) (1) THE SECRETARY SHALL ADOPT A PREFERRED DRUG ~~FORMULARY~~ LIST ~~AND A DRUG BENEFIT MANAGEMENT PROGRAM TO MANAGE THE DRUG THERAPIES OF ENROLLEES~~ TO OFFSET COSTS IN THE ~~PROGRAM'S~~ STATE PRESCRIPTION DRUG ~~BENEFITS~~ PROGRAM ~~AS RECOMMENDED BY THE STATE PHARMACEUTICAL AND THERAPEUTICS COMMITTEE UNDER § 15-118.1 OF THE HEALTH - GENERAL ARTICLE~~.

(2) THE PREFERRED DRUG LIST ADOPTED BY THE SECRETARY SHALL:

(I) BE CONSISTENT WITH THE RECOMMENDATIONS OF THE STATE PHARMACEUTICAL AND THERAPEUTICS COMMITTEE UNDER § 15-118.1 OF THE HEALTH - GENERAL ARTICLE;

(II) PROVIDE FOR COVERAGE OF DRUGS IN EVERY THERAPEUTIC CLASS; AND

(III) OFFER A CHOICE OF PHARMACEUTICALS OR BIOLOGICAL ENTITIES WITHOUT AN ADMINISTRATIVE PREFERENCE FOR EACH THERAPEUTIC CLASS IN WHICH THERE ARE TWO OR MORE PHARMACEUTICAL OR BIOLOGICAL ENTITIES APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION.

~~(2)~~ (3) THE DEPARTMENT ~~SHALL ATTEMPT TO NEGOTIATE PRESCRIPTION DRUG REBATE AGREEMENTS WITH MANUFACTURERS OF PRESCRIPTION DRUGS~~ MAY CONTRACT WITH A PERSON TO:

(I) CONDUCT NEGOTIATIONS FOR SUPPLEMENTAL REBATES; AND

(II) ADMINISTER THE PREFERRED DRUG LIST AND PRIOR AUTHORIZATION PROCEDURES AUTHORIZED UNDER THIS SECTION.

~~(3) IF A MANUFACTURER OF PRESCRIPTION DRUGS HAS REFUSED TO ENTER INTO A PRESCRIPTION DRUG REBATE AGREEMENT, THE DEPARTMENT SHALL MAKE A PROMPT DETERMINATION OF WHETHER TO PLACE A MANUFACTURER'S PRESCRIPTION DRUG ON THE PREFERRED DRUG FORMULARY.~~

(4) SUBJECT TO THE PROVISIONS OF ~~PARAGRAPH (5)~~ PARAGRAPHS (5), (6), (7), AND (8) OF THIS SUBSECTION, THE DEPARTMENT SHALL ESTABLISH PRIOR AUTHORIZATION REQUIREMENTS FOR PRESCRIPTION DRUGS LISTED ON THE PREFERRED DRUG ~~FORMULARY~~ LIST ESTABLISHED UNDER THIS SUBSECTION.

(5) THE DEPARTMENT MAY NOT ESTABLISH PRIOR AUTHORIZATION REQUIREMENTS OR RESTRICT COVERAGE FOR MEDICATIONS USED TO TREAT:

(I) MENTAL ILLNESSES, INCLUDING ATYPICAL ANTIPSYCHOTIC MEDICATIONS, CONVENTIONAL ANTIPSYCHOTIC MEDICATIONS, AND ACTIVE SEROTONIN RE-UPTAKE INHIBITORS; AND

(II) THE HUMAN IMMUNODEFICIENCY VIRUS (HIV) OR THE ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS).

~~(5)~~ (6) FOR ANY PRESCRIPTION DRUG SUBJECT TO PRIOR AUTHORIZATION, THE DEPARTMENT SHALL IMPLEMENT PROCEDURES TO ENSURE THAT:

(I) THE DEPARTMENT RESPONDS TO A REQUEST FOR PRIOR ~~CONSULTATION~~ AUTHORIZATION BY TELEPHONE OR OTHER TELECOMMUNICATION DEVICE WITHIN 24 HOURS AFTER RECEIPT OF A REQUEST FOR PRIOR ~~CONSULTATION~~ AUTHORIZATION; AND

(II) A 72-HOUR SUPPLY OF THE PRESCRIBED DRUG WILL BE PROVIDED IN AN EMERGENCY OR WHEN THE DEPARTMENT DOES NOT PROVIDE A RESPONSE WITHIN 24 HOURS.

(7) (I) THE DEPARTMENT SHALL ESTABLISH AN APPEALS PROCESS FOR A STATE PRESCRIPTION DRUG PROGRAM RECIPIENT OR AN AUTHORIZED PRESCRIBER TO APPEAL AN ADVERSE DECISION BY THE DEPARTMENT REGARDING PRIOR AUTHORIZATION TO A LICENSED PHYSICIAN.

(II) THE DEPARTMENT SHALL ENSURE THAT A STATE PRESCRIPTION DRUG PROGRAM RECIPIENT OR AN AUTHORIZED PRESCRIBER RECEIVES A RESPONSE TO AN APPEAL WITHIN 48 HOURS.

(8) THE DEPARTMENT SHALL ENSURE THAT THE PRIOR AUTHORIZATION FOR A PRESCRIPTION DRUG IS VALID FOR AT LEAST A 1-YEAR PERIOD IF AN INDIVIDUAL HAS RECEIVED PRIOR AUTHORIZATION FOR:

(I) A PRESCRIPTION DRUG TO TREAT A CHRONIC CONDITION; OR

(II) CONTRACEPTIVE DRUGS AND ITEMS.

~~(6)~~ (9) THE DEPARTMENT SHALL:

(I) INFORM THE STATE PHARMACEUTICAL AND THERAPEUTICS COMMITTEE UNDER § 15-118.1 OF THE HEALTH - GENERAL ARTICLE OF ANY DECISIONS REGARDING PRESCRIPTION DRUGS SUBJECT TO PRIOR AUTHORIZATION; AND

(II) ~~PUBLISH AND DISSEMINATE THE PREFERRED DRUG FORMULARY TO ALL ENROLLEES IN THE PROGRAM AND RETAIL PHARMACIES IN THE STATE THAT PARTICIPATE IN THE PROGRAM; AND~~ ANNUALLY PUBLISH THE PREFERRED DRUG LIST IN THE MARYLAND REGISTER AND MAINTAIN AN UPDATED VERSION OF THE PREFERRED DRUG LIST ON THE DEPARTMENT'S INTERNET WEBSITE.

~~(III) ESTABLISH AN APPEALS PROCESS FOR AN ENROLLEE OF THE PROGRAM TO APPEAL A PREFERRED DRUG FORMULARY DECISION BY THE DEPARTMENT.~~

~~(7) (I) THE DEPARTMENT SHALL DEVELOP AND IMPLEMENT A DRUG BENEFIT MANAGEMENT PROGRAM TO MANAGE THE DRUG THERAPIES OF PROGRAM ENROLLEES WHO ARE USING A SIGNIFICANT NUMBER OF PRESCRIPTION DRUGS EACH MONTH.~~

~~(II) THE MANAGEMENT PROCESS MAY INCLUDE COMPREHENSIVE, PHYSICIAN-DIRECTED MEDICAL-RECORD REVIEWS, CLAIMS ANALYSES, AND CASE EVALUATIONS TO DETERMINE THE MEDICAL NECESSITY AND APPROPRIATENESS OF A PATIENT'S TREATMENT PLAN AND DRUG THERAPIES.~~

~~(8) THE DEPARTMENT MAY CONTRACT WITH A PRIVATE ORGANIZATION TO:~~

~~(I) NEGOTIATE REBATES FROM MANUFACTURERS OF PRESCRIPTION DRUGS ON BEHALF OF THE DEPARTMENT;~~

~~(II) ADMINISTER THE PREFERRED DRUG FORMULARY AND PRIOR AUTHORIZATION PROCEDURES REQUIRED UNDER THIS SUBSECTION; AND~~

~~(III) PROVIDE SERVICES FOR A DRUG BENEFIT MANAGEMENT PROGRAM.~~

~~SECTION 2. AND BE IT FURTHER ENACTED, That the Department of Budget and Management shall report to the General Assembly on or before January 1, 2003, in accordance with § 2-1246 of the State Government Article, on the total amount of rebates obtained by the pharmacy benefits manager that administers the State employees prescription drug benefits program, whether the State is receiving an appropriate level of the rebates obtained, and the cost savings to the State that would result from development of a preferred drug formulary and a drug benefit management program in the State employees prescription drug benefits program.~~

~~SECTION 3. AND BE IT FURTHER ENACTED, That for fiscal year 2003 only and from those additional revenues resulting from this Act that are credited to the General Fund for fiscal year 2003, and from no other funds, and subject to the provisions of law relating to budgetary procedure to the extent applicable, the amount specified below, or as much thereof as required to accomplish the designated purpose, is hereby appropriated and authorized to be disbursed from as much of those additional revenues as are received by the State:~~

~~MEDICAL CARE PROGRAMS ADMINISTRATION~~

~~MQ01.03 Medical Care Provider Reimbursement~~

~~In addition to the amount appropriated in the Budget Bill for fiscal year 2003, to supplement the appropriation for fiscal year 2003, the following amount to be used to pay for payment of Medical Assistance Provider Reimbursements authorized by the General Assembly:~~

~~General Fund Appropriation $23,500,000~~

~~Federal Fund Appropriation $10,000,000~~

SECTION 2. AND BE IT FURTHER ENACTED, That:

(a) The Department of Health and Mental Hygiene shall consult with representatives of the pharmaceutical and pharmacy industries, authorized prescribers, and patient advocates to identify and implement alternative cost containment measures.

(b) In fiscal year 2003, any cost savings obtained as the result of alternative cost containment measures implemented under subsection (a) of this section, other than revenues from supplemental rebates, shall be used by the Department to offset pharmacy reimbursement cost containment measures.

(c) (1) The Department may not implement a reduction in the pharmacy reimbursement rate until October 1, 2002.

(2) By October 1, 2002, if additional cost savings obtained as a result of alternative cost containment measures are not sufficient to ensure that on an annualized basis the pharmacy cost containment assumed in the fiscal 2003 budget will be achieved, the Department shall implement cost containment measures with respect to pharmacy reimbursement in a manner that achieves the level of savings that would have been achieved if the pharmacy reimbursement reduction took effect on July 1, 2002.

(d) On or before October 1, 2002, the Department shall report, in accordance with § 2-1246 of the State Government Article, to the Senate Finance Committee, the Senate Budget and Taxation Committee, the House Economic Matters Committee, and the House Environmental Matters Committee on the measures that have been taken to identify and implement alternative cost containment measures and the projected cost savings attributed to these measures.

(e) On or before October 1, 2002, the Department shall report, in accordance with § 2-1246 of the State Government Article, to the Senate Finance Committee, the Senate Budget and Taxation Committee, the House Economic Matters Committee, and the House Environmental Matters Committee on the pharmacy dispensing fee for the Medicaid program and MPAP. In preparing the report, the Department shall consult with representatives from the community and independent pharmacies. The report may include the following:

(1) an analysis of the dispensing fee structure in other states;

(2) an analysis of current reports and literature concerning dispensing fees in state prescription drug programs; and

(3) a review of industry supplied surveys concerning the time and associated costs of dispensing.

SECTION ~~4.~~ 3. AND BE IT FURTHER ENACTED, That this Act shall take effect July 1, 2002.