HOUSE BILL 1122

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CF SB 623

By: **Delegates Hammen, Shriver, Hurson, Rawlings, Taylor, Boutin, Branch, Brinkley, Cole, C. Davis, Dobson, Dypski, Finifter, Gladden, Glassman, Harrison, James, Krysiak, Malone, McHale, Morhaim, Nathan-Pulliam, Oaks, Parrott, Phillips, Riley, Sher, Stern, ~~and Zirkin~~ Zirkin, Klausmeier, Frush, Billings, Cane, D. Davis, Owings, Weir, Elliott, Redmer, Stull, Boutin, and Hubbard**

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Committee Report: Favorable with amendments
House action: Adopted with floor amendments
Read second time: April 6, 2002

CHAPTER_____

AN ACT concerning

Prescription Drug ~~Manufacturer Rebates - Supplementary Appropriation~~ Spending Control Program - Medical Care Programs Administration

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~~, 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~~; authorizing the Department to negotiate certain supplemental rebates; providing for the effect of the Department's negotiating of or failure to negotiate a supplemental rebate with a manufacturer; establishing a State Pharmaceutical and Therapeutics Committee within the Department for the purpose of developing recommendations for 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; authorizing the Department to establish prior authorization requirements for certain drugs and drug classes under certain circumstances; requiring the Department to provide a certain reimbursement to pharmacists under certain circumstances, to establish a certain hotline for responding to requests for prior authorization, to inform the Committee of certain decisions, to publish a certain preferred drug ~~formulary~~ list, to provide certain notice of changes in a certain preferred drug ~~formulary~~ list, and to establish a certain appeals process; requiring denials of prior authorization to be approved by an authorized prescriber; prohibiting the Department from establishing prior authorization requirements for certain medications; ~~requiring~~ authorizing the Department to develop and implement ~~a~~ certain drug benefit management ~~program~~ programs; 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 that any savings achieved by the Department as a result of drug management and utilization programs be used for certain purposes; declaring the intent of the General Assembly regarding the establishment of a preferred drug list; authorizing the Department to implement certain measures to encourage the use of certain drugs on a preferred drug list; requiring the Department to work with certain representatives in establishing a prior authorization process; requiring the Department to consult with certain representatives to identify and implement certain cost containment measures; prohibiting the Department from taking certain actions; requiring the Department to implement certain cost containment measures under certain circumstances; requiring the Department to submit certain reports on or before certain dates; authorizing the Department of Budget and Management to examine certain methods of aggregating the State's purchasing power for prescription drugs; requiring the Department of Budget and Management to submit a report on or before a certain date; ~~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, to establish certain prior authorization requirements for prescription drugs, to inform a certain committee of certain decisions, to publish a certain preferred drug formulary, to establish a certain appeals process, to contract with a private entity for certain duties, and to make a certain report by a certain date; defining certain terms; providing for the legislative appropriation for a certain fiscal year of certain revenues derived as a result of this Act; and generally relating to prescription drug manufacturer rebates and a supplementary appropriation for a certain fiscal year for the Medical Care Programs Administration.~~ defining certain terms; and generally relating to the prescription drug spending control program in the Department of Health and Mental Hygiene.

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 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 DRUGS.

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

(4) "EMERGENCY" INCLUDES A SITUATION IN WHICH EMERGENCY SERVICES, AS DEFINED IN § 19-701(D) OF THIS ARTICLE, ARE PROVIDED.

~~(3)~~ (5) (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)~~ (6) "MARYLAND PHARMACY ASSISTANCE PROGRAM" OR "MPAP" MEANS THE MARYLAND PHARMACY ASSISTANCE PROGRAM ESTABLISHED UNDER § 15-124 OF THIS SUBTITLE.

~~(5)~~ (7) "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.

(8) "PREFERRED DRUG LIST" MEANS A LIST OF DRUGS NOT SUBJECT TO PRIOR AUTHORIZATION.

~~(6) "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 DRUGS COVERED BY 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~~,~~ AND 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.

(D) (1) THE DEPARTMENT MAY NEGOTIATE SUPPLEMENTAL REBATES FROM MANUFACTURERS FOR THE PROGRAM AND MPAP.

(2) (I) THE DEPARTMENT'S NEGOTIATION OF A SUPPLEMENTAL REBATE WITH A MANUFACTURER OR FAILURE TO NEGOTIATE A SUPPLEMENTAL REBATE MAY NOT BE A FACTOR IN THE CONSIDERATION OF A MANUFACTURER'S PRODUCT FOR INCLUSION ON THE PREFERRED DRUG LIST; AND

~~(C) (1) THE DEPARTMENT MAY ESTABLISH A PREFERRED DRUG FORMULARY 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) THE DEPARTMENT MAY CONTRACT WITH A PERSON TO CONDUCT NEGOTIATIONS FOR SUPPLEMENTAL REBATES AUTHORIZED UNDER SUBSECTION (C) OF THIS SECTION.~~

(E) THE DEPARTMENT, ~~AT ITS OWN DISCRETION~~ TO THE EXTENT POSSIBLE, MAY ELECT TO RECEIVE ~~OTHER~~ THE FOLLOWING PROGRAM BENEFITS THAT OFFSET A MEDICAID OR MPAP EXPENDITURE ~~IN LIEU OF A SUPPLEMENTAL REBATE UNDER SUBSECTION (C) 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; AND

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

(5) INITIATIVES TO PREVENT FRAUD AND ABUSE; AND

~~(5)~~ (6) 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) (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~~ PHYSICIANS ~~IN THE STATE~~ LICENSED IN MARYLAND;

(II) FIVE MEMBERS SHALL BE ~~LICENSED~~ PHARMACISTS ~~IN THE STATE~~ LICENSED IN MARYLAND; 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~~ PHYSICIANS LICENSED IN MARYLAND THAT PARTICIPATE IN THE PROGRAM;

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

(III) ~~LICENSED~~ PHYSICIANS LICENSED IN MARYLAND OR ~~LICENSED~~ PHARMACISTS LICENSED IN MARYLAND 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;~~ OF THE DRUG, INCLUDING;

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; AND

(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) OF THIS SECTION ARE PROVIDED WITH THE OPPORTUNITY TO PRESENT EVIDENCE SUPPORTING INCLUSION OF A PRODUCT ON THE PREFERRED DRUG FORMULARY; 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 FOR THE STATE PRESCRIPTION DRUG PROGRAM BY CONSIDERING THE CLINICAL EFFICACY, SAFETY, AND COST-EFFECTIVENESS OF A PRODUCT; AND~~

~~4. MAKE RECOMMENDATIONS TO THE DEPARTMENT 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~~,~~ AND 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~~,~~ AND 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) (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.

(H) (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:

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

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

(III) MAY NOT LIMIT OR EXCLUDE COVERAGE OF A DRUG COMMONLY USED IN PEDIATRIC PATIENTS SOLELY ON THE BASIS THAT THE DRUG HAS NOT BEEN TESTED OR APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION FOR PEDIATRIC USE.

~~(H)~~ (I) (1) SUBJECT TO THE PROVISIONS OF PARAGRAPHS (2) ~~AND (3)~~, (3), (4), (5), AND (6) 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, ACTIVE SEROTONIN RE-UPTAKE INHIBITORS, ATYPICAL ANTIDEPRESSANTS, AND DRUGS TO TREAT EPILEPSY AND OTHER CENTRAL NERVOUS SYSTEM BRAIN DISORDERS;

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

(III) END-STAGE RENAL DISEASE; AND

(IV) ANY OTHER CONDITION OR ILLNESS AS RECOMMENDED BY THE COMMITTEE.

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

(I) THE DEPARTMENT RESPONDS TO AND RESOLVES 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) 1. A ~~72 HOUR~~ SUPPLY OF THE PRESCRIBED DRUG EQUAL TO THE SUPPLY SPECIFIED IN THE PRESCRIPTION, NOT INCLUDING REFILLS, WILL BE PROVIDED IN AN EMERGENCY OR WHEN THE DEPARTMENT DOES NOT PROVIDE A RESPONSE WITHIN 24 HOURS; AND

2. THE DEPARTMENT REIMBURSES A PHARMACIST FOR DRUGS DISPENSED IN AN EMERGENCY OR WHEN THE DEPARTMENT DOES NOT PROVIDE A RESPONSE WITHIN 24 HOURS;

(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 DENIALS OF PRIOR AUTHORIZATION ARE APPROVED BY AN AUTHORIZED PRESCRIBER WITHIN THE DEPARTMENT.

(4) THE DEPARTMENT SHALL ESTABLISH A 24-HOUR TELEPHONE HOTLINE FOR THE PURPOSE OF RESPONDING TO REQUESTS FOR PRIOR AUTHORIZATION.

(5) (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.

(III) THE DEPARTMENT MAY CONTRACT WITH A THIRD PARTY ADMINISTRATOR TO CONDUCT APPEALS UNDER THIS SECTION.

(6) 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)~~ (J) 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~~

(2) 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) 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) NOTWITHSTANDING ANY OTHER PROVISION OF LAW, ANY SAVINGS ACHIEVED BY THE DEPARTMENT AS A RESULT OF DRUG MANAGEMENT AND UTILIZATION PROGRAMS SHALL BE USED AS FOLLOWS:

(1) PRIORITY SHALL BE GIVEN TO THE REIMBURSEMENT OF PROVIDERS FOR THE ENTIRE AMOUNT OF THE PROGRAM FEE FOR OUTPATIENT MENTAL HEALTH TREATMENT FOR DUALLY-ELIGIBLE INDIVIDUALS, INCLUDING:

(I) ANY AMOUNT ORDINARILY WITHHELD AS A PSYCHIATRIC EXCLUSION; AND

(II) ANY COPAYMENT NOT COVERED UNDER MEDICARE; AND

(2) ANY ADDITIONAL SAVINGS ACHIEVED SHALL BE USED TO:

(I) OFFSET THE COST OF PRESCRIPTION DRUGS IN THE PROGRAM OR MPAP; OR

(II) FUND THE MARYLAND PHARMACY DISCOUNT PROGRAM AS AUTHORIZED BY CHAPTERS 134 AND 135 OF THE ACTS OF 2001.

~~(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:

(1) (I) THE ~~AMOUNT OF SUPPLEMENTAL REBATES OR OTHER~~ COST CONTAINMENT MEASURES IMPLEMENTED UNDER THIS SECTION ~~AND~~;

(II) THEIR EFFECT ON PRESCRIPTION DRUG EXPENDITURES IN THE PROGRAM AND MPAP;

(III) THE AMOUNT OF SAVINGS ACHIEVED THROUGH THE IMPLEMENTATION OF COST CONTAINMENT MEASURES; AND

(IV) THE USES FOR WHICH THE SAVINGS ACHIEVED WERE EXPENDED IN ACCORDANCE WITH SUBSECTION (L) OF THIS SECTION; AND

(2) THE FEDERAL WAIVERS AND PROGRAM PLAN AMENDMENTS NECESSARY TO IMPLEMENT THE PROVISIONS OF THIS SECTION, INCLUDING:

(I) THE FEDERAL WAIVERS AND PROGRAM PLAN AMENDMENTS SOUGHT BY THE DEPARTMENT; AND

(II) IF APPLICABLE, AN EXPLANATION AS TO WHY ANY FEDERAL WAIVERS AND PROGRAM PLAN AMENDMENTS IDENTIFIED AS NECESSARY TO IMPLEMENT THE PROVISIONS OF THIS SECTION WERE NOT SOUGHT BY THE DEPARTMENT.

~~**Article - State Personnel and Pensions**~~

~~2-503.~~

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

~~(2) THE DEPARTMENT SHALL ATTEMPT TO NEGOTIATE PRESCRIPTION DRUG REBATE AGREEMENTS WITH MANUFACTURERS OF PRESCRIPTION DRUGS.~~

~~(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) OF THIS SUBSECTION, THE DEPARTMENT SHALL ESTABLISH PRIOR AUTHORIZATION REQUIREMENTS FOR PRESCRIPTION DRUGS LISTED ON THE PREFERRED DRUG FORMULARY ESTABLISHED UNDER THIS SUBSECTION.~~

~~(5) 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 BY TELEPHONE OR OTHER TELECOMMUNICATION DEVICE WITHIN 24 HOURS AFTER RECEIPT OF A REQUEST FOR PRIOR CONSULTATION; 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.~~

~~(6) 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;~~

~~(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~~

~~(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 it is the intent of the General Assembly that, in making recommendations for the establishment of a preferred drug list pursuant to this Act, the Pharmaceutical and Therapeutics Committee established under § 15-118.1 of the Health - General Article as enacted by this Act shall:

(1) in addition to the clinical efficacy and cost-effectiveness of a particular drug therapy, consider the impact of a drug therapy's use on total health care costs, including hospitalization, physician services, and ancillary services;

(2) take into account the needs of program recipients, such as ease of drug therapy administration, rate of compliance with drug therapy instructions, and access to transportation;

(3) make recommendations to the Department of Health and Mental Hygiene on the types of drugs and dosage amounts that should be made available to program recipients on an emergency basis, without the need for prior authorization or in the event prior authorization cannot be readily obtained;

(4) make recommendations to the Department of Health and Mental Hygiene on the duration of a prior authorization approval; and

(5) consistent with the provisions of this Act regarding membership, be comprised of individuals having experience with the needs of program recipients, including individuals with experience in the following areas:

(i) pediatrics;

(ii) geriatrics;

(iii) long-term care;

(iv) the State's Medical Assistance Program, including HealthChoice;

(v) a pharmaceutical and therapeutics committee of a hospital;

(vi) a pharmaceutical and therapeutics committee of a pharmacy benefit manager;

(vii) mental health; and

(viii) emergency medicine.

SECTION 3. AND BE IT FURTHER ENACTED, That the Department of Health and Mental Hygiene may implement measures to encourage the use of medically appropriate generic drugs and those brand name drugs on a preferred drug list, including:

(1) the use of tiered copayments for Medicaid and the Maryland Pharmacy Assistance Program provided that the amounts set for those copayments do not result in an increase in total copayment collections;

(2) the use of differential dispensing fees to pharmacies provided that the amounts set for those dispensing fees remains revenue neutral;

(3) the use of consultation payments to pharmacies, similar to those used in the State Employee Health Benefits Plan, to encourage communication between patients, prescribers, and pharmacists regarding cost-effective drug therapies; and

(4) the implementation of education programs on the use of preferred drugs for prescribers that participate in the Medicaid and Maryland Pharmacy Assistance Programs.

SECTION 4. AND BE IT FURTHER ENACTED, That the Department of Health and Mental Hygiene, in establishing the prior authorization process required under this Act, shall work with representatives of the pharmaceutical and pharmacy industries, authorized prescribers, and patient advocates to ensure the process is not unduly burdensome on prescribers, pharmacists, or program recipients and participants. It is the intent of the General Assembly that prior authorization not be used as the exclusive tool for compliance with the preferred drug list.

SECTION 5. AND BE IT FURTHER ENACTED, That:

(1) 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.

(2) (i) the Department of Health and Mental Hygiene may not implement a reduction in the pharmacy reimbursement rate until October 1, 2002.

(ii) the Department of Health and Mental Hygiene may not increase the total copayment collection from enrollees in the Medicaid program, including enrollees in managed care organizations.

(3) on or before 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 of Health and Mental Hygiene 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.

(4) on or before October 1, 2002, the Department of Health and Mental Hygiene 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.

(5) on or before October 1, 2002, the Department of Health and Mental Hygiene 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 and Maryland Pharmacy Assistance Programs. In preparing the report, the Department of Health and Mental Hygiene shall consult with representatives from the community and independent pharmacies. The report may include the following:

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

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

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

SECTION 6. AND BE IT FURTHER ENACTED, That the Department of Budget and Management may examine and implement appropriate methods of aggregating the State's purchasing power for prescription drugs, including participation in a multi-state prescription drug purchasing program, in order to maximize volume discounts on the cost of prescription drugs. On or before December 1, 2002, the Department of Budget and Management shall, in accordance with § 2-1246 of the State Government Article, report to the Senate Finance Committee, the Senate Budget and Taxation Committee, the House Environmental Matters Committee, and the House Economic Matters Committee, on the efforts of the Department of Budget and Management to aggregate the State's purchasing power for prescription drugs and any savings achieved.

SECTION ~~4.~~ 7. AND BE IT FURTHER ENACTED, That this Act shall take effect July 1, 2002.