

BY: Environmental Matters Committee

AMENDMENTS TO HOUSE BILL NO. 1122

(First Reading File Bill)

AMENDMENT NO. 1

On page 1, in the sponsor line, after “Hammen” insert “, Shriver”; in the same line, strike “and Zirkin” and substitute “Zirkin, Klausmeier, Frush, Billings, Cane, D. Davis, Owings, Weir, Elliott, Redmer, Stull, Boutin, and Hubbard”; in line 2, strike “Manufacturer Rebates - Supplementary Appropriation” and substitute “Spending Control Program”; in line 6, strike “formularies” and substitute “lists”; in line 8, strike “formulary” and substitute “list”; strike beginning with the first comma in line 8 down through “circumstances” in line 10; after line 10, insert “authorizing the Department to negotiate certain supplemental rebates;”; in line 12, after “developing” insert “recommendations for”; in the same line, strike “formulary” and substitute “list”; strike beginning with “providing” in line 12 down through “Committee;” in line 14; in line 19, after “Committee” insert a semicolon; strike beginning with the first comma in line 19 down through “Committee;” in line 21; in line 24, after “to” insert “provide a certain reimbursement to pharmacists under certain circumstances, to establish a certain hotline for responding to requests for prior authorization, to”; in lines 25 and 26, in each instance, strike “formulary” and substitute “list”; in line 27, after “process;” insert “requiring denials of prior authorization to be approved by an authorized prescriber; prohibiting the Department from establishing prior authorization requirements for certain medications;”; in the same line, strike “requiring” and substitute “authorizing”; in line 28, strike “a”; in the same line, strike “program” and substitute “programs”; and in line 31, after “date;” insert “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

(Over)

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;”.

On pages 1 and 2, strike beginning with “requiring” in line 31 on page 1 down through “Administration.” in line 11 on page 2 and substitute “defining certain terms; and generally relating to the prescription drug spending control program in the Department of Health and Mental Hygiene.”.

On page 2, strike in their entirety lines 22 through 26, inclusive.

AMENDMENT NO. 2

On page 3, in line 15, strike “IN” and substitute “TO”; in the same line, strike “FORMULARY” and substitute “LIST”; after line 29, insert:

“(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.”;

in line 30, strike “(2)” and substitute “(3)”; after line 32, insert:

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

and in line 33, strike “(3)” and substitute “(5)”.

On page 4, in lines 1 and 4, strike “(4)” and “(5)”, respectively, and substitute “(6)” and “(7)”, respectively; after line 6, insert:

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

strike in their entirety lines 7 through 11, inclusive; after line 11, insert:

“(B) THIS SECTION DOES NOT APPLY TO DRUGS COVERED BY MANAGED CARE ORGANIZATIONS UNDER § 15-103 OF THIS SUBTITLE.”;

in line 12, strike “(B)” and substitute “(C)”; strike beginning with the comma in line 12 down through the comma in line 13; in line 14, strike the first comma and substitute “AND”; strike beginning with the second comma in line 14 down through “PROGRAM” in line 15; in lines 15 and 16, strike “: (1)”; in line 16, after “INCLUDE” insert “:

(1)”;

in the same line, strike “FORMULARY” and substitute “LIST”; in line 18, strike “ESTABLISHES”; and after line 20, insert:

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

AMENDMENT NO. 3

On pages 4 and 5, strike in their entirety the lines beginning with line 21 on page 4 through line 25 on page 5, inclusive.

AMENDMENT NO. 4

On page 5, in line 26, strike “AT ITS OWN DISCRETION” and substitute “TO THE EXTENT POSSIBLE”; in line 27, strike “OTHER” and substitute “THE FOLLOWING”; strike beginning with “IN” in line 27 down through “SECTION” in line 28; in line 30, strike “DISEASE MANAGEMENT PROGRAMS;” and substitute “INTENSIFIED BENEFITS MANAGEMENT PROGRAMS FOR:

- (I) NEW PROGRAM AND MPAP ENROLLEES;
- (II) HIGH COST DRUG UTILIZERS; AND
- (III) RESIDENTS OF LONG-TERM CARE FACILITIES;”;

(Over)

in line 33, after “PARTICIPANT” insert a colon; and strike in its entirety line 34 and substitute:

“(I) COUNSELING; AND

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

(5) INITIATIVES TO PREVENT FRAUD AND ABUSE; AND”.

On page 6, in line 1, strike “(5)” and substitute “(6)”; strike beginning with “WITH” in line 1 down through “APPLICABLE” in line 3 and substitute “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”;

in lines 6 and 22, in each instance, strike “FORMULARY” and substitute “LIST”; in line 7, strike “11” and substitute “13”; in lines 10, 12, 17, 18, and 20, in each instance, strike “LICENSED”; in lines 10 and 11 and 12 and 13, in each instance, strike “IN THE STATE” and substitute “LICENSED IN MARYLAND”; in line 14, strike “ONE MEMBER SHALL BE A” and substitute “THREE MEMBERS SHALL BE”; in the same line, strike “REPRESENTATIVE” and substitute “REPRESENTATIVES DOMICILED IN THE STATE”; in lines 17 and 20, in each instance, after “PHYSICIANS” insert “LICENSED IN MARYLAND”; and in lines 18 and 20, in each instance, after “PHARMACISTS” insert “LICENSED IN MARYLAND”.

AMENDMENT NO. 5

On page 7, in line 8, strike “FORMULARY” and substitute “LIST”; in line 9, strike “, SAFETY, AND COST-EFFECTIVENESS OF A PRODUCT;” and substitute “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;

in line 12, strike the semicolon and substitute a period; strike in their entirety lines 13 through 32, inclusive; in line 35, strike the first comma and substitute “AND”; in the same line, strike beginning with the second comma through the second “PROGRAM”; and in line 36, strike “FORMULARIES” and substitute “LISTS”.

AMENDMENT NO. 6

On page 8, in line 2, strike the first comma and substitute “AND”; in the same line, strike “, AND STATE PRESCRIPTION DRUG PROGRAM”; in line 3, strike “FORMULARIES” and substitute “LISTS”; in the same line, strike “FORMULARY” and substitute “LIST”; after line 15, insert:

“(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;

(Over)

(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.”;

in line 16, strike “(H)” and substitute “(I)”; in the same line, strike “AND (3)” and substitute “, (3), (4), (5), AND (6)”; in line 19, after “DRUGS” insert “NOT”; in lines 20, 23, and 26, in each instance, strike “FORMULARY” and substitute “LIST”; after line 27, insert:

“(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.”;

in line 28, strike “(2)” and substitute “(3)”; in line 30, after “TO” insert “AND RESOLVES”; in the same line, after “REQUEST” insert “FROM AN AUTHORIZED PRESCRIBER”; in lines 31 and

32, in each instance, strike “CONSULTATION” and substitute “AUTHORIZATION”; in line 32, strike “AND”; in line 33, after “(II)” insert “1.”; in the same line, strike “72-HOUR”; in the same line, after “DRUG” insert “EQUAL TO THE SUPPLY SPECIFIED IN THE PRESCRIPTION, NOT INCLUDING REFILLS.”; in line 35, after “HOURS” insert “; 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

(Over)

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.”;

in line 36, strike “(I)” and substitute “(J)”;

and in line 38, after “AUTHORIZATION;” insert “AND”.

AMENDMENT NO. 7

On page 9, strike in their entirety lines 1 through 3, inclusive, and substitute:

“(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.”;

strike in their entirety lines 4 through 20, inclusive; after line 25, insert:

“(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 DUALY-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.”;

in line 26, strike “(L)” and substitute “(M)”; in line 28, after “ON” insert “;

(1) (I)”;

in the same line, strike”AMOUNT OF SUPPLEMENTAL REBATES OR OTHER”; in line 29, after “MEASURES” insert “IMPLEMENTED”; in the same line, strike “AND” and substitute “;

(II)”;

and in line 30, after “MPAP” insert “;

(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

(Over)

FEDERAL WAIVERS AND PROGRAM PLAN AMENDMENTS IDENTIFIED AS NECESSARY TO IMPLEMENT THE PROVISIONS OF THIS SECTION WERE NOT SOUGHT BY THE DEPARTMENT”.

AMENDMENT NO. 8

On pages 9 through 11, strike beginning with line 31 on page 9 through line 29 on page 11, inclusive.

AMENDMENT NO. 9

On page 11, after line 29, insert:

“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

(Over)

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.”;

and in line 30, strike “4.” and substitute “7.”.