

BY: Budget and Taxation Committee

AMENDMENTS TO SENATE BILL NO. 623

(First Reading File Bill)

AMENDMENT NO. 1

On page 1, in the sponsor line, strike “and Bromwell” and substitute “, Astle, Bromwell, DeGrange, Della, Exum, Frosh, Hafer, Hooper, Kelley, Middleton, Roesser, Teitelbaum, Van Hollen, Ruben, Lawlah, and Currie”; strike beginning with “Supplementary” in line 2 down through “Administration” in line 3 and substitute “State Funded Prescription Drug Programs”; in line 6, strike “is required to include”; in line 8, strike the first comma and substitute “and to”; in the same line, strike the second comma and substitute a semicolon; strike beginning with “and” in line 8 down through “circumstances;” in line 10; strike beginning with “providing” in line 12 down through “Committee;” in line 14; in line 22, after “circumstances;” insert “requiring the Department to make certain preferred drug list decisions based on certain criteria;”; in line 24, after “circumstances;” insert “prohibiting the Department from establishing prior authorization for certain medications;”; in line 26, strike “provide certain notice of changes in a certain preferred drug formulary;”; in line 27, strike “a”; in the same line, strike “process” and substitute “processes”; strike beginning with “requiring” in line 27 down through “program;” in line 28; in line 31, after “date;” insert “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;”; strike beginning with “requiring” in line 31 down through “program;” in line 33; strike beginning with “attempt” in line 34 down through “drugs” in line 35 and substitute “establish a preferred drug list, to negotiate certain supplemental rebates”.

On page 2, in line 2, strike the second “a”; in line 3, strike “process” and substitute “processes”; in the same line, strike “to contract with a private entity for certain duties;”; in line 4, after “date;” insert “prohibiting the Department from establishing prior authorization for certain”.

(Over)

medications;”; strike beginning with “providing” in line 4 down through “Act;” in line 6 and substitute “requiring the Department of Health and Mental Hygiene to report to certain committees of the General Assembly at a certain time;”; strike beginning with “and” in line 7 down through “Administration” in line 8 and substitute “and State funded prescription drug programs”; and after line 18, insert:

“BY repealing and reenacting, with amendments,

Article - Health - General

Section 15-124(b)

Annotated Code of Maryland

(2000 Replacement Volume and 2001 Supplement)”.

AMENDMENT NO. 2

On page 3, in line 13, strike “IN” and substitute “TO”; after line 27, 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 OR NONPRESCRIPTION DRUGS.”;

and in lines 28 and 31, strike “(2)” and “(3)”, respectively, and substitute “(3)” and “(4)”, respectively.

AMENDMENT NO. 3

On page 4, in lines 1, 4, and 7, strike “(4)”, “(5)”, and “(6)”, respectively, and substitute “(5)”, “(6)”, and “(7)”, respectively; after line 11, insert:

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

in line 12, strike “(B)” and substitute “(C)”; in line 15, strike the colon; in line 16, strike “(1)”; in the same line, after “INCLUDE” insert “;

(1)”;

in line 18, strike “ESTABLISHES”; and in line 21, strike “(C) (1)” and substitute “(D)”.

On pages 4 and 5, strike beginning with “THAT” in line 24 on page 4 down through “REBATES” in line 22 on page 5.

On page 5, in lines 23 and 26, strike “(D)” and “(E)”, respectively, and substitute “(E)” and “(F)”, respectively; in line 24, strike “(C)” and substitute “(D)”; in line 26, strike “, AT ITS OWN DISCRETION, MAY ELECT TO RECEIVE” and substitute “MAY IMPLEMENT”; in line 27, strike “THAT OFFSET A” and substitute “TO OFFSET”; in the same line strike “EXPENDITURE” and substitute “EXPENDITURES”; in line 28, after the first “OF” insert “, OR IN ADDITION TO,”; and in the same line, strike “(C)” and substitute “(D)”; 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;”;

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

- “(I) COUNSELING;
- (II) EDUCATION WITH AN EMPHASIS ON COST-EFFECTIVE DRUG THERAPIES; AND
- (III) FRAUD AND ABUSE INITIATIVES; AND”.

On page 6, strike beginning with “WITH” in line 1 down through “APPLICABLE” in line 3 and substitute “TO REDUCE PROGRAM OR MPAP EXPENDITURES, INCLUDING:”

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- (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".

AMENDMENT NO. 4

On page 6, in line 4, strike "(F)" and substitute "(G)"; in line 7, strike "11" and substitute "13"; in lines 10, 12, 17, 18, and 20, in each instance, after "LICENSED" insert "MARYLAND"; in line 14, strike "ONE MEMBER SHALL BE A" and substitute "THREE MEMBERS SHALL BE"; and in the same line, strike "REPRESENTATIVE" and substitute "REPRESENTATIVES DOMICILED IN THE STATE".

On page 7, in line 8, strike beginning with "CLINICAL" in line 8 down through "PRODUCT;" in line 9, and substitute ":

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;";

in line 15, strike "(C)" and substitute "(D)"; strike beginning with "CLINICAL" in line 28 down through "; AND" in line 29, and substitute ":

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";

and in line 30, after "DEPARTMENT" insert "OF BUDGET AND MANAGEMENT".

On page 8, in line 7, strike “(G)” and substitute “(H)”; after line 15, insert:

“(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.”;

in line 16, strike “(H)” and substitute “(J)”; in the same line, strike “AND (3)” and substitute “, (3), (4), AND (5)”; in line 19, after “DRUGS” insert “NOT”; after line 27, insert:

“(2) 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

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ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS).”;
in line 28, strike “(2)” and substitute “(3)”; in line 30, after “REQUEST” insert “FROM AN AUTHORIZED PRESCRIBER”; in line 31, strike “CONSULTATION” and substitute “AUTHORIZATION”; in line 32, strike “CONSULTATION” and substitute “AUTHORIZATION”;
after line 35, insert:

“(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.”;

in line 36, strike “(I)” and substitute “(K)”; and in line 38, after “AUTHORIZATION;” insert “AND”.

AMENDMENT NO. 5

On page 9, strike beginning with “PUBLISH” in line 1 down through “AND” in line 3 and substitute “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; in lines 21 and 26, strike “(K)” and “(L)”, respectively, and substitute “(L)” and “(M)”, respectively; and after line 30, insert:

“(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.

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(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.”.

AMENDMENT NO. 6

On page 9, strike beginning with “AND” in line 34 down through “ENROLLEES” in line 35 and substitute “TO OFFSET COSTS”; in line 35, strike “PROGRAM’S” and substitute “STATE”; in the same line strike “BENEFITS”; and strike beginning with “AS” in line 35 down through “ARTICLE” in line 37 and substitute “.

(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”.

On page 10, in line 1, strike “(2)” and substitute “(3)”; strike beginning with “SHALL” in line 1 down through “DRUGS” in line 2 and substitute “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”;

strike in their entirety lines 3 through 6, inclusive; in line 7, strike “PARAGRAPH (5)” and substitute “PARAGRAPHS (5), (6), (7), and (8)”; after line 10, insert:

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“(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).”;

in line 11, strike “(5)” and substitute “(6)”; in line 14, strike “CONSULTATION” and substitute “AUTHORIZATION”; in line 15, strike “CONSULTATION” and substitute “AUTHORIZATION”; after line 18, insert:

“(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.”;

in line 19, strike “(6)” and substitute “(9)”; in line 22, after “AUTHORIZATION;” insert “AND”;

and strike beginning with “PUBLISH” in line 23 down through “AND” in line 25 and substitute “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.”.

On pages 10 and 11, strike in their entirety the lines beginning with line 26 on page 10 through line 29 on page 11, inclusive.

AMENDMENT NO. 7

On page 11, after line 29, insert:

“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

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§ 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.”;

and in line 30, strike “4.” and substitute “3.”.

AMENDMENT NO. 8

On page 1, in line 6, strike “formularies” and substitute “lists”; in lines 8 and 12, in each instance, strike “formulary” and substitute “list”; and in line 25, strike “formulary, to” and substitute “list.”.

On page 2, in line 2, strike “formulary” and substitute “list”.

On page 3, in line 13, strike “FORMULARY” and substitute “LIST”.

On page 4, in lines 16 and 22, in each instance, strike “FORMULARY” and substitute “LIST”.

On page 6, in lines 6 and 22, in each instance, strike “FORMULARY” and substitute “LIST”.

On page 7, in lines 8, 17, and 27, in each instance, strike “FORMULARY” and substitute “LIST”; and in line 36, strike “FORMULARIES” and substitute “LISTS”.

On page 8, in line 3, strike “FORMULARIES” and substitute “LISTS”; and in lines 3, 20, 23, and 26, in each instance, strike “FORMULARY” and substitute “LIST”.

On page 9, in line 33, strike “FORMULARY” and substitute “LIST”.

On page 10, in line 10, strike “FORMULARY” and substitute “LIST”.