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# By: Delegates Hammen, 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 Introduced and read first time: February 8, 2002

Assigned to: Environmental Matters

# A BILL ENTITLED

1 AN ACT concerning

# Prescription Drug Manufacturer Rebates - Supplementary Appropriation Medical Care Programs Administration

FOR the purpose of requiring the Department of Health and Mental Hygiene to 4 establish a State prescription drug spending control program that may include 5 certain preferred drug formularies and is required to include a certain process 6 7 for managing drug therapies; authorizing the Department to establish a 8 preferred drug formulary, negotiate certain supplemental rebates, and to enter 9 into certain agreements with manufacturers of generic drugs; providing that 10 certain rebates may be less than a certain amount under certain circumstances; 11 establishing a State Pharmaceutical and Therapeutics Committee within the 12 Department for the purpose of developing a preferred drug formulary; providing 13 that an agreement to pay a certain supplemental rebate will guarantee certain 14 consideration by the Committee; specifying the membership, terms, officers, 15 quorum, required meetings, and duties of the Committee; authorizing the 16 Secretary of Health and Mental Hygiene to remove a member of the Committee 17 for good cause; providing that to the extent feasible, the Committee is required 18 to perform a certain review and may make certain recommendations; requiring 19 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 20 Committee; requiring the Department to ensure a certain product review by the 21 22 Committee under certain circumstances; authorizing the Department to 23 establish prior authorization requirements for certain drugs and drug classes 24 under certain circumstances; requiring the Department to inform the 25 Committee of certain decisions, to publish a certain preferred drug formulary, to 26 provide certain notice of changes in a certain preferred drug formulary, and to 27 establish a certain appeals process; requiring the Department to develop and 28 implement a certain drug benefit management program; authorizing the 29 Department to seek federal waivers, amendments to the State Medical 30 Assistance Program plan, or adopt regulations; requiring the Department to 31 make a certain annual report by a certain date; requiring the Department of

32 Budget and Management to establish a certain preferred drug formulary and a

- 1 certain drug benefits management program; requiring the Department of
- 2 Budget and Management to attempt to negotiate certain agreements with
- 3 manufacturers of prescription drugs, to establish certain prior authorization
- 4 requirements for prescription drugs, to inform a certain committee of certain
- 5 decisions, to publish a certain preferred drug formulary, to establish a certain
- 6 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
- 8 legislative appropriation for a certain fiscal year of certain revenues derived as 9 a result of this Act; and generally relating to prescription drug manufacturer
- a result of this Act; and generally relating to prescription drug manufacturer
   rebates and a supplementary appropriation for a certain fiscal year for the
- 10 redates and a supplementary appropriation for a cer 11 Medical Care Programs Administration.
- 12 BY repealing and reenacting, with amendments,
- 13 Article Health General
- 13 Afficie Health 14 Section 15-118
- 15 Annotated Code of Maryland
- 16 (2000 Replacement Volume and 2001 Supplement)
- 17 BY adding to
- 18 Article Health General
- 19 Section 15-118.1
- 20 Annotated Code of Maryland
- 21 (2000 Replacement Volume and 2001 Supplement)
- 22 BY adding to
- 23 Article State Personnel and Pensions
- 24 Section 2-503(e)
- 25 Annotated Code of Maryland
- 26 (1997 Replacement Volume and 2001 Supplement)
- 27 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF
- 28 MARYLAND, That the Laws of Maryland read as follows:
- 29

# Article - Health - General

30 15-118.

31 (a) (1) Unless the prescriber directs otherwise on the form or on an attached 32 signed certification of need, the generic form of the drug authorized under § 12-504 of 33 the Health Occupations Article shall be used to fill the prescription.

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

37 (b) (1) Except as provided under paragraph (2) of this subsection, the
38 Program shall establish maximum reimbursement levels for the drug products for

1 which there is a generic equivalent authorized under § 12-504 of the Health

2 Occupations Article, based on the cost of the generic product.

3 (2) If a prescriber directs a specific brand name drug, the reimbursement 4 level shall be based on the cost of the brand name product.

5 (c) (1) Except as provided under paragraph (4) of this subsection and unless 6 the change is made by an emergency regulation, the Program shall notify all

7 pharmacies under contract with the Program in writing of changes in the

8 Pharmaceutical Benefit Program rules or requirements at least 30 days before the

9 change is effective.

10 (2) Changes that require 30 days' advance written notice under 11 paragraph (1) of this subsection are:

12 (i) Exclusion of coverage for classes of drugs as specified by 13 contract;

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

15(iii)CHANGES IN THE PREFERRED DRUG FORMULARY16ESTABLISHED UNDER § 15-118.1 OF THIS SUBTITLE; AND

17

(IV) Selection of new prescription claims processors.

18(3)If the Program fails to provide advance notice as required under19paragraph (1) of this subsection, it shall honor and pay in full any claim under the20Program rules or requirements that existed before the change for 30 days after the

21 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
24 § 12-504 of the Health Occupations Article.

25 (d) The Secretary shall adopt regulations to carry out the provisions of this 26 section.

27 15-118.1.

28 (A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE MEANINGS 29 INDICATED.

30 (2) "COMMITTEE" MEANS THE STATE PHARMACEUTICAL AND
 31 THERAPEUTICS COMMITTEE ESTABLISHED UNDER SUBSECTION (F) OF THIS
 32 SECTION.

33(3)(I)"MANUFACTURER" MEANS A MANUFACTURER OF34PRESCRIPTION DRUGS AS DEFINED IN 42 U.S.C. § 1396R-8 (K)(5).

35(II)"MANUFACTURER" INCLUDES A SUBSIDIARY OR AFFILIATE OF36 A MANUFACTURER.

1 (4) "MARYLAND PHARMACY ASSISTANCE PROGRAM" OR "MPAP" MEANS 2 THE MARYLAND PHARMACY ASSISTANCE PROGRAM ESTABLISHED UNDER § 15-124 3 OF THIS SUBTITLE.

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

7 (6) "STATE PRESCRIPTION DRUG PROGRAM" MEANS THE PRESCRIPTION
8 DRUG BENEFITS PROGRAM FOR STATE EMPLOYEES IN THE STATE EMPLOYEE AND
9 RETIREE HEALTH AND WELFARE BENEFITS PROGRAM DEVELOPED AND
10 ADMINISTERED BY THE SECRETARY OF BUDGET AND MANAGEMENT UNDER TITLE 2,
11 SUBTITLE 5 OF THE STATE PERSONNEL AND PENSIONS ARTICLE.

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

16 (1) MAY INCLUDE A PREFERRED DRUG FORMULARY IN ACCORDANCE 17 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.

21 (C) (1) THE DEPARTMENT MAY ESTABLISH A PREFERRED DRUG
22 FORMULARY FOR THE PROGRAM AND MPAP IN ACCORDANCE WITH THE PROVISIONS
23 OF 42 U.S.C. § 1396R-8, AND THIS SECTION AND MAY NEGOTIATE SUPPLEMENTAL
24 REBATES FROM MANUFACTURERS FOR THE PROGRAM AND MPAP THAT ARE NO LESS
25 THAN 10% OF THE AVERAGE MANUFACTURER PRICE AS DEFINED IN 42 U.S.C. § 1936
26 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.

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

1(I)THE REBATE REQUIRED BY TITLE XIX OF THE SOCIAL2SECURITY ACT EXCEEDS 25%;

3 (II) THE SUPPLEMENTAL REBATE UNDER PARAGRAPH (1) OF THIS 4 SUBSECTION EXCEEDS 25%; OR

5 (III) THE ADDITION OF THE REBATES IN ITEMS (I) AND (II) OF THIS 6 PARAGRAPH EXCEEDS 25%.

7 (4) THERE IS NO UPPER LIMIT ON THE SUPPLEMENTAL REBATES THE 8 DEPARTMENT MAY NEGOTIATE UNDER THIS SECTION.

9 (5) THE DEPARTMENT MAY DETERMINE THAT SPECIFIC DRUG 10 PRODUCTS, BRAND-NAME DRUGS, OR GENERIC DRUGS, ARE COMPETITIVE AT LOWER 11 REBATE PERCENTAGES THAN THE PERCENTAGE REQUIRED IN PARAGRAPH (1) OF 12 THIS SUBSECTION.

13 (6) (I) AN AGREEMENT TO PAY THE SUPPLEMENTAL REBATE
14 PERCENTAGE NEGOTIATED BY THE DEPARTMENT UNDER THIS SUBSECTION WILL
15 GUARANTEE A MANUFACTURER THAT THE COMMITTEE WILL CONSIDER A PRODUCT
16 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.

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

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

26 (E) THE DEPARTMENT, AT ITS OWN DISCRETION, MAY ELECT TO RECEIVE
27 OTHER PROGRAM BENEFITS THAT OFFSET A MEDICAID OR MPAP EXPENDITURE IN
28 LIEU OF A SUPPLEMENTAL REBATE UNDER SUBSECTION (C) OF THIS SECTION
29 INCLUDING:

30 (1) DISEASE MANAGEMENT PROGRAMS;

31 (2) DRUG PRODUCT DONATION PROGRAMS;

32 (3) DRUG UTILIZATION CONTROL PROGRAMS;

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

1 (5)OTHER SERVICES OR ADMINISTRATIVE PROGRAMS WITH 2 GUARANTEED SAVINGS TO THE PROGRAM OR MPAP IN THE FISCAL YEAR IN WHICH 3 THE SUPPLEMENTAL REBATE WOULD HAVE BEEN APPLICABLE. 4 THERE IS A STATE PHARMACEUTICAL AND THERAPEUTICS (F) (1)5 COMMITTEE WITHIN THE DEPARTMENT FOR THE PURPOSE OF DEVELOPING A 6 PREFERRED DRUG FORMULARY UNDER 42 U.S.C. § 1396R-8 AND THIS SECTION. THE COMMITTEE CONSISTS OF THE FOLLOWING 11 MEMBERS 7 (2)8 APPOINTED BY THE GOVERNOR AND CONSISTENT WITH THE REOUIREMENTS OF 42 9 U.S.C. § 1396R-8: 10 (I) FIVE MEMBERS SHALL BE LICENSED PHYSICIANS IN THE 11 STATE; 12 (II) FIVE MEMBERS SHALL BE LICENSED PHARMACISTS IN THE 13 STATE; AND 14 ONE MEMBER SHALL BE A CONSUMER REPRESENTATIVE. (III) IN APPOINTING THE MEMBERS TO THE COMMITTEE, THE GOVERNOR 15 (3)16 SHALL MAKE BEST EFFORTS TO ENSURE REPRESENTATION OF: 17 LICENSED PHYSICIANS THAT PARTICIPATE IN THE PROGRAM; (I) LICENSED PHARMACISTS EMPLOYED BY PARTICIPATING 18 (II) 19 RETAIL PHARMACIES; AND LICENSED PHYSICIANS OR LICENSED PHARMACISTS WITH 20 (III) 21 EXPERIENCE IN DEVELOPING OR PRACTICING UNDER A PREFERRED DRUG 22 FORMULARY. 23 (4)THE TERM OF A MEMBER IS 3 YEARS. (I) A MEMBER MAY NOT BE APPOINTED FOR MORE THAN TWO 24 (II) 25 CONSECUTIVE FULL TERMS. (III) AT THE END OF A TERM, A MEMBER CONTINUES TO SERVE 26 27 UNTIL A SUCCESSOR IS APPOINTED. THE SECRETARY MAY REMOVE ANY MEMBER OF THE 28 (IV) 29 COMMITTEE FOR GOOD CAUSE. A MEMBER OF THE COMMITTEE MAY NOT RECEIVE COMPENSATION 30 (5)31 FOR SERVING ON THE COMMITTEE, BUT IS ENTITLED TO REIMBURSEMENT FOR 32 EXPENSES UNDER THE STANDARD STATE TRAVEL REGULATIONS, AS PROVIDED IN 33 THE STATE.

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

1 (7) A QUORUM OF THE COMMITTEE SHALL BE A MAJORITY OF THE 2 APPOINTED MEMBERSHIP OF THE COMMITTEE.
<ul> <li>3 (8) THE COMMITTEE SHALL MEET NOT LESS THAN EVERY 3 MONTHS</li> <li>4 AND MAY MEET AT OTHER TIMES AT THE DISCRETION OF THE CHAIRMAN AND</li> <li>5 MEMBERS.</li> </ul>
6 (9) THE COMMITTEE:
<ul> <li>7 (I) SHALL DEVELOP RECOMMENDATIONS FOR A PREFERRED DRUG</li> <li>8 FORMULARY FOR THE PROGRAM AND MPAP BY CONSIDERING THE CLINICAL</li> <li>9 EFFICACY, SAFETY, AND COST-EFFECTIVENESS OF A PRODUCT;</li> </ul>
10 (II) MAY MAKE RECOMMENDATIONS TO THE DEPARTMENT 11 REGARDING THE PRIOR AUTHORIZATION OF ANY PRESCRIBED DRUG COVERED BY 12 THE PROGRAM AND MPAP;
<ul> <li>(III) SHALL ENSURE THAT MANUFACTURERS THAT HAVE AGREED</li> <li>TO PROVIDE A SUPPLEMENTAL REBATE TO THE PROGRAM AND MPAP UNDER</li> <li>SUBSECTION (C) OF THIS SECTION ARE PROVIDED WITH THE OPPORTUNITY TO</li> <li>PRESENT EVIDENCE SUPPORTING INCLUSION OF A PRODUCT ON THE PREFERRED</li> <li>DRUG FORMULARY; AND</li> </ul>
18(IV)IN CONSULTATION WITH THE DEPARTMENT OF BUDGET AND19MANAGEMENT, SHALL:
201.REVIEW WHETHER THE STATE IS RECEIVING AN21APPROPRIATE LEVEL OF REBATES IN THE STATE PRESCRIPTION DRUG PROGRAM;
<ol> <li>22 2. MAKE RECOMMENDATIONS ON MECHANISMS TO</li> <li>23 MAXIMIZE PRESCRIPTION DRUG COST SAVINGS IN THE STATE PRESCRIPTION DRUG</li> <li>24 PROGRAM INCLUDING A DRUG BENEFIT MANAGEMENT PROGRAM TO MANAGE THE</li> <li>25 DRUG THERAPIES OF STATE PRESCRIPTION DRUG PROGRAM ENROLLEES WHO ARE</li> <li>26 USING A SIGNIFICANT NUMBER OF PRESCRIPTION DRUGS EACH MONTH;</li> </ol>
<ol> <li>DEVELOP A PREFERRED DRUG FORMULARY FOR THE</li> <li>STATE PRESCRIPTION DRUG PROGRAM BY CONSIDERING THE CLINICAL EFFICACY,</li> <li>SAFETY, AND COST-EFFECTIVENESS OF A PRODUCT; AND</li> </ol>
304.MAKE RECOMMENDATIONS TO THE DEPARTMENT31REGARDING THE PRIOR AUTHORIZATION OF ANY PRESCRIBED DRUG COVERED BY32THE STATE PRESCRIPTION DRUG PROGRAM.
33 (10) TO THE EXTENT FEASIBLE, THE COMMITTEE:
34 (I) SHALL REVIEW ALL DRUG CLASSES INCLUDED IN THE 35 PROGRAM, MPAP, AND STATE PRESCRIPTION DRUG PROGRAM PREFERRED DRUG 36 FORMULARIES AT LEAST EVERY 12 MONTHS: AND

36 FORMULARIES AT LEAST EVERY 12 MONTHS; AND

7

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

5 (11) THE DEPARTMENT SHALL PROVIDE STAFF SUPPORT FOR THE 6 COMMITTEE.

7 (G) (1) THE DEPARTMENT SHALL PROVIDE TIMELY NOTICE AND ENSURE
8 THAT ANY DRUG THAT HAS BEEN APPROVED OR HAD ANY OF ITS PARTICULAR USES
9 APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION UNDER A
10 PRIORITY REVIEW CLASSIFICATION WILL BE REVIEWED BY THE COMMITTEE AT THE
11 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.

16 (H) (1) SUBJECT TO THE PROVISIONS OF PARAGRAPHS (2) AND (3) OF THIS
17 SUBSECTION, THE DEPARTMENT MAY ESTABLISH PRIOR AUTHORIZATION
18 REQUIREMENTS FOR:

19(I)PRESCRIPTION DRUGS LISTED ON THE PREFERRED DRUG20FORMULARY ESTABLISHED UNDER THIS SECTION;

21(II)PRESCRIPTION DRUGS FOR SPECIFIC POPULATIONS OF22PROGRAM RECIPIENTS AND MPAP PARTICIPANTS REGARDLESS OF WHETHER THE23DRUGS ARE LISTED ON THE PREFERRED DRUG FORMULARY; AND

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

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

30(I)THE DEPARTMENT RESPONDS TO A REQUEST FOR PRIOR31CONSULTATION BY TELEPHONE OR OTHER TELECOMMUNICATION DEVICE WITHIN3224 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.

36 (I) THE DEPARTMENT SHALL:

INFORM THE COMMITTEE OF ANY DECISIONS REGARDING
 PRESCRIPTION DRUGS SUBJECT TO PRIOR AUTHORIZATION;

1 (2) PUBLISH AND DISSEMINATE THE PREFERRED DRUG FORMULARY TO 2 ALL MEDICAID PROVIDERS, MPAP PROVIDERS, AND PARTICIPATING RETAIL 3 PHARMACIES IN THE STATE; AND

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

7 (J) (1) THE DEPARTMENT SHALL DEVELOP AND IMPLEMENT A DRUG
8 BENEFIT MANAGEMENT PROGRAM TO MANAGE THE DRUG THERAPIES OF PROGRAM
9 RECIPIENTS AND MPAP PARTICIPANTS WHO ARE USING A SIGNIFICANT NUMBER OF
10 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.

15 (3) THE DEPARTMENT MAY CONTRACT WITH A PRIVATE ORGANIZATION
16 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.

21 (K) THE DEPARTMENT MAY:

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

24(2)ADOPT REGULATIONS TO CARRY OUT THE PROVISIONS OF THIS25SECTION.

(L) 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.

31

Article - State Personnel and Pensions

32 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.

1(2)THE DEPARTMENT SHALL ATTEMPT TO NEGOTIATE PRESCRIPTION2DRUG REBATE AGREEMENTS WITH MANUFACTURERS OF PRESCRIPTION DRUGS.

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

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

11(5)FOR ANY PRESCRIPTION DRUG SUBJECT TO PRIOR AUTHORIZATION,12THE DEPARTMENT SHALL IMPLEMENT PROCEDURES TO ENSURE THAT:

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

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

19 (6) THE DEPARTMENT SHALL:

20(I)INFORM THE STATE PHARMACEUTICAL AND THERAPEUTICS21COMMITTEE UNDER § 15-118.1 OF THE HEALTH - GENERAL ARTICLE OF ANY22DECISIONS 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

26 (III) ESTABLISH AN APPEALS PROCESS FOR AN ENROLLEE OF THE
27 PROGRAM TO APPEAL A PREFERRED DRUG FORMULARY DECISION BY THE
28 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.

37 (8) THE DEPARTMENT MAY CONTRACT WITH A PRIVATE ORGANIZATION38 TO:

11	HOUSE BILL 1122
1 2	(I) NEGOTIATE REBATES FROM MANUFACTURERS OF PRESCRIPTION DRUGS ON BEHALF OF THE DEPARTMENT;
3 4	(II) ADMINISTER THE PREFERRED DRUG FORMULARY AND PRIOR AUTHORIZATION PROCEDURES REQUIRED UNDER THIS SUBSECTION; AND
5 6	(III) PROVIDE SERVICES FOR A DRUG BENEFIT MANAGEMENT PROGRAM.
9 10 11 12 13	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.
17 18 19 20	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:
22	MEDICAL CARE PROGRAMS ADMINISTRATION
23	MQ01.03 Medical Care Provider Reimbursement
26	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:
28	General Fund Appropriation \$23,500,000

29 Federal Fund Appropriation \$10,000,000
30 SECTION 4. AND BE IT FURTHER ENACTED, That this Act shall take effect
31 July 1, 2002.