

(PRE-FILED)

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**By: Chairman, Finance Committee (Departmental - Health and Mental Hygiene)**

Requested: October 25, 1995

Introduced and read first time: January 10, 1996

Assigned to: Finance

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Committee Report: Favorable with amendments

Senate action: Adopted

Read second time: February 2, 1996

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CHAPTER \_\_\_\_\_

1 AN ACT concerning

2 **Maryland Medical Assistance Program and Maryland Pharmacy Assistance Program -**  
3 **Prescription Drugs - Generic Substitutions**

4 FOR the purpose of altering the prescription drugs for which the generic forms are  
5 required to fill certain prescriptions under the Maryland Medical Assistance  
6 Program; repealing certain publication requirements of the Medical Assistance  
7 Program related to certain generic substitutions; establishing a certain exception to  
8 ~~contain~~ certain notice requirements regarding certain changes in pharmaceutical  
9 rules or requirements under the Maryland Medical Assistance Program and the  
10 Maryland Pharmacy Assistance Program; authorizing the Department of Health  
11 and Mental Hygiene to waive a certain requirement under a certain circumstance;  
12 providing for the effective dates of this Act; and generally relating to the  
13 substitution of generic forms of certain prescription drugs under the Maryland  
14 Medical Assistance Program and the Maryland Pharmacy Assistance Program.

15 BY repealing and reenacting, with amendments,  
16 Article - Health - General  
17 Section 15-118 and 15-124(b)(1) and (c)  
18 Annotated Code of Maryland  
19 (1994 Replacement Volume and 1995 Supplement)

20 BY repealing and reenacting, with amendments,  
21 Article - Health - General  
22 Section 15-124(b)(1) and (c)  
23 Annotated Code of Maryland  
24 (1994 Replacement Volume and 1995 Supplement)

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1 (As enacted by Chapter 401 of the Acts of the General Assembly of 1991, as  
2 amended by Chapter 98 of the Acts of the General Assembly of 1993, and as  
3 amended by Chapter 573 of the Acts of the General Assembly of 1995)

4 Preamble

5 WHEREAS, Generic equivalents of prescription drugs are far less expensive than  
6 brand name drugs; and

7 WHEREAS, Several pharmacy insurance programs, such as the State employee  
8 program, require substitution of therapeutically equivalent generic forms of drugs as soon  
9 as the generic forms are included in "Approved Drug Products with Therapeutic  
10 Equivalence Evaluations", a publication by the U.S. Department of Health and Human  
11 Services that is also known as the "Orange Book"; and

12 WHEREAS, Current law requires the Maryland Medical Assistance Program to  
13 publish additions to the Program list of equivalent generic drugs 60 days before a  
14 substitution may be required; and

15 WHEREAS, As compared with other pharmacy insurance programs, these  
16 required delays double the amount of time before State pharmacy insurance programs  
17 may institute cost-saving substitutions of generic drugs; and

18 WHEREAS, In its Point-of-Sale system, the Department of Health and Mental  
19 Hygiene now has the ability to advise pharmaceutical providers electronically regarding  
20 the payment of a generic drug in the State formulary, thus providing prompt and  
21 meaningful notice; and

22 WHEREAS, Repeal of current notice requirements would provide for substantial  
23 cost savings of approximately \$250,000 in State funds each year by allowing the State to  
24 require generic substitutions on a more timely and efficient basis; now, therefore,

25 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF  
26 MARYLAND, That the Laws of Maryland read as follows:

27 **Article - Health - General**

28 15-118.

29 (a) [The forms that are used in prescribing and billing for drugs under the  
30 Program shall include the following statement, if applicable: This prescription shall be  
31 filled with a generic equivalent as authorized by State law, unless theprescriber directs  
32 otherwise in writing.] ~~A PRESCRIPTION, FORM, OR AN ELECTRONIC COMMUNICATION~~  
33 ~~THROUGH THE POINT OF SALE SYSTEM THAT IS USED TO PRESCRIBE OR BILL FOR~~  
34 ~~DRUGS SHALL SPECIFICALLY ON ITS FACE THAT THE GENERIC~~  
35 ~~EQUIVALENT OF A PRESCRIPTION DRUG IS REQUIRED UNLESS OTHERWISE~~  
36 ~~DIRECTED IN WRITING BY THE PRESCRIBER.~~

37 (b) (1) Unless the prescriber directs otherwise ~~AND INCLUDES A MEDICAL~~  
38 ~~REASON WHY THE GENERIC CANNOT BE USED~~ on the form or on an attached signed  
39 certification of need, the generic form of the drug authorized under § 12-508 of the  
40 Health Occupations Article shall be used to fill the prescription[, except for drugs

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1 generally not available in the State, drugs that have low utilization, or drugs lacking  
2 significant cost differential between the interchangeable products].

3 (2) IF THE APPROPRIATE GENERIC DRUG IS NOT GENERALLY  
4 AVAILABLE, THE DEPARTMENT MAY WAIVE THE REQUIREMENT FOR GENERIC  
5 SUBSTITUTION UNDER PARAGRAPH (1) OF THIS SUBSECTION.

6 ~~(B)~~ (1) [The Program shall publish a list of drugs with therapeutic  
7 equivalence as defined in § 12-508 of the Health Occupations Article that are generally  
8 available within the State, have sufficient utilization, are packaged for administration or  
9 patient use in a manner that avoids any potential adverse impact on efficacy of treatment,  
10 and have sufficient cost differential between products.

11 (2) The] EXCEPT AS PROVIDED UNDER PARAGRAPH (2) OF THIS  
12 SUBSECTION, THE Program shall establish maximum reimbursement levels for the drug  
13 products [listed under paragraph (1) of this subsection based on the cost of the available  
14 generic products] FOR WHICH THERE IS A GENERIC EQUIVALENT AUTHORIZED  
15 UNDER § 12-508 OF THE HEALTH OCCUPATIONS ARTICLE, BASED ON THE COST OF  
16 THE GENERIC PRODUCT.

17 (2) IF A PRESCRIBER DIRECTS A SPECIFIC BRAND NAME DRUG, THE  
18 REIMBURSEMENT LEVEL SHALL BE BASED ON THE COST OF THE BRAND NAME  
19 PRODUCT.

20 [(3) Additions to the Program list of interchangeable drugs shall be effective  
21 60 days after the publication of the Program list or supplements to the Program list  
22 including the changes.

23 (4) Drug products disqualified from being used as a generic substitute in  
24 accordance with § 12-508 of the Health Occupations Article shall be deleted from the  
25 Program list of interchangeable drugs concurrently and without further action by the  
26 Department.]

27 ~~(C)~~ (1) [Unless] EXCEPT AS PROVIDED UNDER PARAGRAPH (4) OF  
28 THIS SUBSECTION AND UNLESS the change is made by an emergency regulation, the  
29 Program shall notify all pharmacies under contract with the Program in writing of changes  
30 in the Pharmaceutical Benefit Program rules or requirements at least 30 days before the  
31 change is effective.

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

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

35 (ii) Changes in prior or preauthorization procedures; and

36 (iii) Selection of new prescription claims processors.

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

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1 (4) NOTWITHSTANDING ANY OTHER PROVISION OF LAW, THE NOTICE  
2 REQUIREMENTS OF THIS SUBSECTION DO NOT APPLY TO THE ADDITION OF NEW  
3 GENERIC DRUGS AUTHORIZED UNDER § 12-508 OF THE HEALTH OCCUPATIONS  
4 ARTICLE.

5 (e) (D) The Secretary shall adopt regulations to carry out the provisions of this  
6 section [and to identify those drugs that meet the criteria required under subsection (c)  
7 of this section].

8 SECTION 2. AND BE IT FURTHER ENACTED, That the Laws of Maryland  
9 read as follows:

10 **Article - Health - General**

11 15-124.

12 (b) (1) (I) Reimbursement under the Maryland Pharmacy Assistance  
13 Program shall be limited to maintenance drugs, anti-infectives, and AZTas specified in  
14 regulations to be issued by the Secretary after consultation with the Maryland  
15 Pharmacists Association.

16 (II) 1. For any drug on the Program's interchangeable druglist, the  
17 Program shall reimburse providers in an amount not more than it would reimburse for the  
18 drug's generic equivalent, unless the individual's physician states, in his or her own  
19 handwriting, on the face of the prescription, that a specific brand is "medically necessary"  
20 ~~AND INCLUDES A MEDICAL REASON WHY THE GENERIC CANNOT BE USED~~ for the  
21 particular patient.

22 2. IF AN APPROPRIATE GENERIC DRUG IS NOT GENERALLY  
23 AVAILABLE, THE DEPARTMENT MAY WAIVE THE REIMBURSEMENT REQUIREMENT  
24 UNDER SUB-SUBPARAGRAPH 1 OF THIS SUBPARAGRAPH.

25 (c) (1) [Unless] EXCEPT AS PROVIDED UNDER PARAGRAPH (4) OF THIS  
26 SUBSECTION AND UNLESS the change is made by an emergency regulation, the Maryland  
27 Pharmacy Assistance Program shall notify all pharmacies under contract with the  
28 Program in writing of changes in the Pharmaceutical Benefit Program rules or  
29 requirements at least 30 days before the change is effective.

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

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

33 (ii) Changes in prior or preauthorization procedures; and

34 (iii) Selection of new prescription claims processors.

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

39 (4) NOTWITHSTANDING ANY OTHER PROVISION OF LAW, THE NOTICE  
40 REQUIREMENTS OF THIS SUBSECTION DO NOT APPLY TO THE ADDITION OF NEW

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1 GENERIC DRUGS AUTHORIZED UNDER § 12-508 OF THE HEALTH OCCUPATIONS  
2 ARTICLE.

3 SECTION 3. AND BE IT FURTHER ENACTED, That the Laws of Maryland  
4 read as follows:

5 **Article - Health - General**

6 15-124.

7 (b) (1) (I) The Maryland Pharmacy Assistance Program shall reimburse  
8 providers for those kinds of items and services that are covered by the pharmacy program  
9 of the Maryland Medical Assistance Program.

10 (II) 1. However, for any drug on the Program's interchangeable  
11 drug list, the Program shall reimburse providers in an amount not more than it would  
12 reimburse for the drug's generic equivalent, unless the individual's physician states, in his  
13 or her own handwriting, on the face of the prescription, that a specific brand is "medically  
14 necessary" ~~AND INCLUDES A MEDICAL REASON WHY THE GENERIC CANNOT BE USED~~  
15 for the particular patient.

16 2. IF AN APPROPRIATE GENERIC DRUG IS NOT GENERALLY  
17 AVAILABLE, THE DEPARTMENT MAY WAIVE THE REIMBURSEMENT REQUIREMENT  
18 UNDER SUB-SUBPARAGRAPH 1 OF THIS SUBPARAGRAPH.

19 (c) (1) [Unless] EXCEPT AS PROVIDED UNDER PARAGRAPH (4) OF THIS  
20 SUBSECTION AND UNLESS the change is made by an emergency regulation, the Maryland  
21 Pharmacy Assistance Program shall notify all pharmacies under contract with the  
22 Program in writing of changes in the Pharmaceutical Benefit Program rules or  
23 requirements at least 30 days before the change is effective.

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

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

27 (ii) Changes in prior or preauthorization procedures; and

28 (iii) Selection of new prescription claims processors.

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

33 (4) NOTWITHSTANDING ANY OTHER PROVISION OF LAW, THE NOTICE  
34 REQUIREMENTS OF THIS SUBSECTION DO NOT APPLY TO THE ADDITION OF NEW  
35 GENERIC DRUGS AUTHORIZED UNDER § 12-508 OF THE HEALTH OCCUPATIONS  
36 ARTICLE.

37 SECTION 4. AND BE IT FURTHER ENACTED, That Section 3 of this Act is  
38 contingent on the taking effect of the termination provision specified in Section 3 of  
39 Chapter 401 of the Acts of the General Assembly of 1991. If that termination provision

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1 takes effect, Section 2 of this Act shall be void. This Act may not be interpreted to have  
2 any effect on that termination provision.

3           SECTION 5. AND BE IT FURTHER ENACTED, That, subject to the  
4 provisions of Section 4 of this Act, this Act shall take effect July 1,1996.