

HOUSE BILL 1004

J1

2lr2637

By: **Delegate Kach**

Introduced and read first time: February 10, 2012

Assigned to: Health and Government Operations

A BILL ENTITLED

1 AN ACT concerning

2 **Medical Assistance Program – Generic Drug Reimbursement Program**

3 FOR the purpose of requiring the Department of Health and Mental Hygiene to
4 establish a generic drug reimbursement program; requiring the program to
5 establish maximum reimbursement levels for certain generic drug products;
6 requiring the program to require a manufacturer of a generic drug product in a
7 certain therapeutic classification to submit certain pricing to the Department
8 for review in order for the manufacturer to participate in the Maryland
9 Medicaid Program; prohibiting the cost of a certain generic drug product from
10 being more than a certain cost as determined by the Department; requiring the
11 Department to determine a certain reimbursement rate for generic drugs in a
12 therapeutic classification based on a certain cost; requiring the Department to
13 adopt certain regulations; and generally relating to the establishment of a
14 generic drug reimbursement program in the Maryland Medical Assistance
15 Program.

16 BY repealing and reenacting, with amendments,
17 Article – Health – General
18 Section 15–118
19 Annotated Code of Maryland
20 (2009 Replacement Volume and 2011 Supplement)

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

23 **Article – Health – General**

24 15–118.

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 (a) (1) Unless the prescriber directs otherwise on the form or on an
2 attached signed certification of need, the generic form of the drug authorized under §
3 12-504 of the Health Occupations Article shall be used to fill the prescription.

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

7 **(B) (1) THE DEPARTMENT SHALL ESTABLISH A GENERIC DRUG**
8 **SUPPLEMENT REBATE PROGRAM.**

9 **(3) THE PROGRAM SHALL INCLUDE A REQUIREMENT THAT A**
10 **MANUFACTURER OF A GENERIC DRUG IN A THERAPEUTIC CLASSIFICATION WITH**
11 **AT LEAST TWO GENERIC DRUG PRODUCTS SUBMIT A REBATE FOR THE GENERIC**
12 **DRUG PRODUCT TO THE DEPARTMENT IN ORDER FOR THE MANUFACTURER TO**
13 **PARTICIPATE IN THE PROGRAM.**

14 **(6) THE DEPARTMENT SHALL ADOPT REGULATIONS TO**
15 **IMPLEMENT THE PROVISIONS OF THIS SUBSECTION.**

16 **[(b)] (C)** (1) Except as provided under paragraph (2) of this subsection,
17 the Program shall establish maximum reimbursement levels for the drug products for
18 which there is a generic equivalent authorized under § 12-504 of the Health
19 Occupations Article, based on the cost of the generic product.

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

22 **[(c)] (D)** (1) Except as provided under paragraph (4) of this subsection
23 and unless the change is made by an emergency regulation, the Program shall notify
24 all pharmacies under contract with the Program in writing of changes in the
25 Pharmaceutical Benefit Program rules or requirements at least 30 days before the
26 change is effective.

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

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

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

32 (iii) Selection of new prescription claims processors.

33 (3) If the Program fails to provide advance notice as required under
34 paragraph (1) of this subsection, it shall honor and pay in full any claim under the

1 Program rules or requirements that existed before the change for 30 days after the
2 postmarked date of the notice.

3 (4) Notwithstanding any other provision of law, the notice
4 requirements of this subsection do not apply to the addition of new generic drugs
5 authorized under § 12–504 of the Health Occupations Article.

6 **[(d)] (E)** The Secretary shall adopt regulations to carry out the provisions of
7 this section.

8 **[(e)] (F)** Except for a prescription for a prescription drug that contains a
9 substance listed in Schedule II or that is determined by the Secretary to present an
10 emerging threat in the State because of increasing abuse or diversion, the provisions
11 of § 21–220(b)(1) of this article shall apply to the Program.

12 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
13 July 1, 2012.