
By: **Delegates Owings and Redmer**

Introduced and read first time: February 6, 2002

Assigned to: Environmental Matters

A BILL ENTITLED

1 AN ACT concerning

2 **Medical Assistance - Pharmaceutical Products - Accessibility and Coverage**
3 **Protection for Enrollees**

4 FOR the purpose of prohibiting the Department of Health and Mental Hygiene from
5 implementing a formulary that is covered by prior authorization in the Medical
6 Assistance Program unless certain provisions are met; prohibiting the
7 Department from restricting coverage of a drug approved by the federal Food
8 and Drug Administration unless the Department has certain data; prohibiting
9 the Department from limiting or excluding coverage of a drug prescribed for a
10 medical condition of a program recipient under certain circumstances; requiring
11 a certain formulary covered by prior authorization to have certain provisions;
12 defining a certain term; and generally relating to a formulary under the Medical
13 Assistance Program.

14 BY adding to
15 Article - Health - General
16 Section 15-118.1
17 Annotated Code of Maryland
18 (2000 Replacement Volume and 2001 Supplement)

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

21 **Article - Health - General**

22 15-118.1.

23 (A) IN THIS SECTION, "FORMULARY" MEANS A LIST OF PRESCRIPTION DRUGS
24 OR DEVICES.

25 (B) THE DEPARTMENT MAY NOT IMPLEMENT A FORMULARY THAT IS
26 COVERED BY PRIOR AUTHORIZATION UNLESS:

27 (1) THE FORMULARY DEVELOPED BY THE DEPARTMENT IS
28 ESTABLISHED BY A PHARMACEUTICAL AND THERAPEUTICS COMMITTEE THAT

1 INCLUDES PRACTICING MARYLAND PHYSICIANS, INCLUDING SPECIALTY
2 PHYSICIANS, PHARMACISTS, PATIENT ADVOCATES, AND OTHERS; AND

3 (2) THE DECISION OF THE COMMITTEE REGARDING ANY LIMITATIONS
4 IMPOSED ON ANY DRUG OR ITS USE FOR A SPECIFIC INDICATION SHALL BE BASED
5 ON SOUND CLINICAL EVIDENCE FOUND IN LABELING, DRUG COMPENDIA, AND PEER
6 REVIEWED CLINICAL LITERATURE PERTAINING TO USE OF THE DRUG IN THE
7 RELEVANT POPULATION.

8 (C) THE DEPARTMENT MAY NOT RESTRICT COVERAGE OF A DRUG APPROVED
9 BY THE FEDERAL FOOD AND DRUG ADMINISTRATION FOR AN INDICATION UNLESS
10 THE DEPARTMENT HAS AT LEAST 6 MONTHS OF DATA REGARDING USE OF THE DRUG
11 FOR TREATING PATIENTS IN THE PROGRAM.

12 (D) THE DEPARTMENT MAY NOT LIMIT OR EXCLUDE COVERAGE OF A DRUG
13 WHEN PRESCRIBED FOR THE MEDICAL CONDITION OF A PROGRAM RECIPIENT IF THE
14 DRUG PREVIOUSLY HAS BEEN APPROVED BY THE DEPARTMENT FOR THE
15 RECIPIENT'S MEDICAL CONDITION.

16 (E) A FORMULARY THAT IS COVERED BY PRIOR AUTHORIZATION AND
17 DEVELOPED BY THE DEPARTMENT SHALL:

18 (1) PROVIDE FOR COVERAGE OF DRUGS IN EVERY THERAPEUTIC CLASS;
19 AND

20 (2) OFFER A CHOICE OF AT LEAST TWO PHARMACEUTICAL OR
21 BIOLOGICAL ENTITIES WITHOUT AN ADMINISTRATIVE PREFERENCE FOR EACH
22 THERAPEUTIC CLASS IN WHICH THERE ARE TWO OR MORE PHARMACEUTICAL OR
23 BIOLOGICAL ENTITIES APPROVED BY THE FEDERAL FOOD AND DRUG
24 ADMINISTRATION.

25 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take
26 effect June 1, 2002.