

SENATE BILL 746

C3

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CF 3lr2175

By: **Senator Middleton**

Introduced and read first time: February 1, 2013

Assigned to: Finance

A BILL ENTITLED

1 AN ACT concerning

2 **Health Insurance – Step Therapy or Fail–First Protocol**

3 FOR the purpose of limiting the duration of a step therapy or fail–first protocol
4 imposed by a certain insurer, nonprofit health service plan, or health
5 maintenance organization; requiring the insurer, nonprofit health service plan,
6 or health maintenance organization to allow a prescriber of a covered
7 prescription drug or device to have certain access to a certain process to override
8 the step therapy or fail–first protocol; requiring the override process to allow a
9 prescriber to override the step therapy or fail–first protocol under certain
10 circumstances; prohibiting the provisions of this Act from being construed to
11 require certain coverage; requiring the Maryland Health Care Commission, in
12 consultation with the Maryland Insurance Administration, to study the use of
13 measures similar to a step therapy or fail–first protocol by health insurance
14 carriers in their coverage of diagnostic imaging and medical and surgical
15 procedures; requiring certain elements to be included in the study; requiring the
16 findings of the study to be reported to the Governor and certain committees of
17 the General Assembly on or before a certain date; defining a certain term;
18 making certain provisions of this Act applicable to health maintenance
19 organizations; and generally relating to step therapy or fail–first protocols in
20 health insurance policies and contracts.

21 BY adding to

22 Article – Health – General
23 Section 19–706(oooo)
24 Annotated Code of Maryland
25 (2009 Replacement Volume and 2012 Supplement)

26 BY adding to

27 Article – Insurance
28 Section 15–140
29 Annotated Code of Maryland

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 (2011 Replacement Volume and 2012 Supplement)

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

4 **Article – Health – General**

5 19–706.

6 (OOOO) THE PROVISIONS OF § 15–140 OF THE INSURANCE ARTICLE
7 APPLY TO HEALTH MAINTENANCE ORGANIZATIONS.

8 **Article – Insurance**

9 15–140.

10 (A) IN THIS SECTION, “STEP THERAPY OR FAIL–FIRST PROTOCOL”
11 MEANS A PROTOCOL THAT ESTABLISHES A SPECIFIC SEQUENCE IN WHICH:

12 (1) PRESCRIPTION DRUGS OR DEVICES THAT ARE MEDICALLY
13 APPROPRIATE FOR A SPECIFIED MEDICAL CONDITION AND A PARTICULAR
14 PATIENT ARE TO BE PRESCRIBED; AND

15 (2) A PREFERRED PRESCRIPTION DRUG OR DEVICE IS
16 PRESCRIBED IN THE SEQUENCE.

17 (B) (1) THIS SECTION APPLIES TO:

18 (I) INSURERS AND NONPROFIT HEALTH SERVICE PLANS
19 THAT PROVIDE HOSPITAL, MEDICAL, OR SURGICAL BENEFITS TO INDIVIDUALS
20 OR GROUPS ON AN EXPENSE–INCURRED BASIS UNDER HEALTH INSURANCE
21 POLICIES OR CONTRACTS THAT ARE ISSUED OR DELIVERED IN THE STATE; AND

22 (II) HEALTH MAINTENANCE ORGANIZATIONS THAT PROVIDE
23 HOSPITAL, MEDICAL, OR SURGICAL BENEFITS TO INDIVIDUALS OR GROUPS
24 UNDER CONTRACTS THAT ARE ISSUED OR DELIVERED IN THE STATE.

25 (2) AN INSURER, NONPROFIT HEALTH SERVICE PLAN, OR HEALTH
26 MAINTENANCE ORGANIZATION THAT PROVIDES COVERAGE FOR PRESCRIPTION
27 DRUGS AND DEVICES THROUGH A PHARMACY BENEFITS MANAGER IS SUBJECT
28 TO THE REQUIREMENTS OF THIS SECTION.

1 **(C) IF AN ENTITY SUBJECT TO THIS SECTION IMPOSES A STEP THERAPY**
2 **OR FAIL–FIRST PROTOCOL ON A COVERED PRESCRIPTION DRUG OR DEVICE FOR**
3 **AN INSURED OR ENROLLEE:**

4 **(1) THE DURATION OF THE STEP THERAPY OR FAIL–FIRST**
5 **PROTOCOL MAY NOT EXCEED THE EARLIER OF:**

6 **(I) THE PERIOD DEEMED NECESSARY BY THE INSURED’S OR**
7 **ENROLLEE’S PRESCRIBER TO DETERMINE THE CLINICAL EFFECTIVENESS OF**
8 **THE PRESCRIPTION DRUG OR DEVICE PREFERRED BY THE ENTITY; OR**

9 **(II) 30 DAYS; AND**

10 **(2) THE ENTITY SHALL ALLOW A PRESCRIBER OF A COVERED**
11 **PRESCRIPTION DRUG OR DEVICE TO HAVE IMMEDIATE ACCESS TO A CLEAR AND**
12 **CONVENIENT PROCESS TO OVERRIDE THE STEP THERAPY OR FAIL–FIRST**
13 **PROTOCOL.**

14 **(D) THE OVERRIDE PROCESS REQUIRED UNDER SUBSECTION (C)(2) OF**
15 **THIS SECTION SHALL ALLOW A PRESCRIBER TO OVERRIDE THE STEP THERAPY**
16 **OR FAIL–FIRST PROTOCOL IF, IN THE PROFESSIONAL JUDGMENT OF THE**
17 **PRESCRIBER:**

18 **(1) THE PRESCRIPTION DRUG OR DEVICE PREFERRED BY THE**
19 **ENTITY HAS BEEN INEFFECTIVE IN TREATING THE INSURED’S OR ENROLLEE’S**
20 **DISEASE OR MEDICAL CONDITION; OR**

21 **(2) BASED ON SOUND CLINICAL, MEDICAL, AND SCIENTIFIC**
22 **EVIDENCE, THE KNOWN RELEVANT PHYSICAL OR MENTAL CHARACTERISTICS OF**
23 **THE INSURED OR ENROLLEE, AND THE KNOWN CHARACTERISTICS OF THE**
24 **TREATMENT REGIMEN OF THE PRESCRIPTION DRUG OR DEVICE PREFERRED BY**
25 **THE ENTITY, THE PRESCRIPTION DRUG OR DEVICE PREFERRED BY THE ENTITY:**

26 **(I) IS LIKELY TO BE INEFFECTIVE OR ADVERSELY AFFECT**
27 **THE INSURED’S OR ENROLLEE’S COMPLIANCE WITH THE TREATMENT REGIMEN;**
28 **OR**

29 **(II) HAS CAUSED OR IS LIKELY TO CAUSE AN ADVERSE**
30 **REACTION OR OTHER HARM TO THE INSURED OR ENROLLEE.**

31 **(E) THIS SECTION MAY NOT BE CONSTRUED TO REQUIRE COVERAGE**
32 **FOR A CONDITION THAT IS NOT:**

1 **(1) ALREADY COVERED BY THE POLICY OR CONTRACT OF THE**
2 **ENTITY SUBJECT TO THIS SECTION; OR**

3 **(2) OTHERWISE REQUIRED TO BE COVERED BY LAW.**

4 SECTION 2. AND BE IT FURTHER ENACTED, That the Maryland Health
5 Care Commission, in consultation with the Maryland Insurance Administration, shall:

6 (1) study the use of measures similar to a step therapy or fail-first
7 protocol by health insurance carriers, including health maintenance organizations, in
8 their coverage of diagnostic imaging and medical and surgical procedures;

9 (2) include in the study:

10 (i) the findings from peer-reviewed medical journals regarding
11 the effect of such measures on patient care, patient outcomes, and health care costs;
12 and

13 (ii) any mechanisms offered by health insurance carriers or
14 required by other states that allow health care providers to override such measures;
15 and

16 (3) on or before January 1, 2014, report the findings of the study to the
17 Governor and, in accordance with § 2-1246 of the State Government Article, the
18 Senate Finance Committee and the House Health and Government Operations
19 Committee.

20 SECTION 3. AND BE IT FURTHER ENACTED, That this Act shall take effect
21 October 1, 2013.