SENATE BILL 622

C3 4lr1975
CF 4lr1976

By: **Senator Middleton**
Introduced and read first time: January 30, 2014
Assigned to: Finance

A BILL ENTITLED

1 AN ACT concerning

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

3 FOR the purpose of requiring the Maryland Health Care Commission to work with
4 certain payors and providers to attain benchmarks for overriding a payor's step
5 therapy or fail–first protocol; requiring the benchmarks to include, on or before
6 a certain date, establishment, by each payor that requires a step therapy or
7 fail–first protocol, of a process for a provider to override the step therapy or
8 fail–first protocol of the payor; limiting the duration of a step therapy or
9 fail–first protocol imposed by a certain insurer, nonprofit health service plan, or
10 health maintenance organization; prohibiting the insurer, nonprofit health
11 service plan, or health maintenance organization from imposing a step therapy
12 or fail–first protocol on an insured or enrollee under certain circumstances;
13 prohibiting certain provisions of this Act from being construed to require certain
14 coverage; repealing certain obsolete provisions of law; defining certain terms;
15 making certain provisions of this Act applicable to health maintenance
16 organizations; and generally relating to step therapy or fail–first protocols in
17 health insurance policies and contracts.

18 BY repealing and reenacting, with amendments,
19 Article – Health – General
20 Section 19–108.2
21 Annotated Code of Maryland
22 (2009 Replacement Volume and 2013 Supplement)

23 BY adding to
24 Article – Health – General
25 Section 19–706(oooo)
26 Annotated Code of Maryland
27 (2009 Replacement Volume and 2013 Supplement)

28 BY adding to

EXPLANATION: **CAPITALS INDICATE MATTER ADDED TO EXISTING LAW**.
[Brackets**]** indicate matter deleted from existing law.

1 Article – Insurance
2 Section 15–141
3 Annotated Code of Maryland
4 (2011 Replacement Volume and 2013 Supplement)

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

7 **Article – Health – General**

8 19–108.2.

9 (a) (1) In this section the following words have the meanings indicated.

10 (2) "Health care service" has the meaning stated in § 15–10A–01 of the
11 Insurance Article.

12 (3) "Payor" means:

13 (i) An insurer or nonprofit health service plan that provides
14 hospital, medical, or surgical benefits to individuals or groups on an expense–incurred
15 basis under health insurance policies or contracts that are issued or delivered in the
16 State;

17 (ii) A health maintenance organization that provides hospital,
18 medical, or surgical benefits to individuals or groups under contracts that are issued
19 or delivered in the State; or

20 (iii) A pharmacy benefits manager that is registered with the
21 Maryland Insurance Commissioner.

22 (4) "Provider" has the meaning stated in § 19–7A–01 of this title.

23 **(5) "STEP THERAPY OR FAIL–FIRST PROTOCOL" HAS THE**
24 **MEANING STATED IN § 15–141 OF THE INSURANCE ARTICLE.**

25 (b) In addition to the duties stated elsewhere in this subtitle, the
26 Commission shall work with payors and providers to attain benchmarks for**:**

27 **(1)** **[**standardizing**]** **STANDARDIZING** and automating the process
28 required by payors for preauthorizing health care services**; AND**

29 **(2) OVERRIDING A PAYOR'S STEP THERAPY OR FAIL–FIRST**
30 **PROTOCOL**.

31 (c) The benchmarks described in subsection (b) of this section shall include:

(1) On or before October 1, 2012 ("Phase 1"), establishment of online access for providers to each payor's:

(i) List of health care services that require preauthorization; and

(ii) Key criteria for making a determination on a preauthorization request;

(2) On or before March 1, 2013 ("Phase 2"), establishment by each payor of an online process for:

(i) Accepting electronically a preauthorization request from a provider; and

(ii) Assigning to a preauthorization request a unique electronic identification number that a provider may use to track the request during the preauthorization process, whether or not the request is tracked electronically, through a call center, or by fax;

(3) On or before July 1, 2013 ("Phase 3"), establishment by each payor of an online preauthorization system to approve:

(i) In real time, electronic preauthorization requests for pharmaceutical services:

1. For which no additional information is needed by the payor to process the preauthorization request; and

2. That meet the payor's criteria for approval;

(ii) Within 1 business day after receiving all pertinent information on requests not approved in real time, electronic preauthorization requests for pharmaceutical services that:

1. Are not urgent; and

2. Do not meet the standards for real–time approval under item (i) of this item; and

(iii) Within 2 business days after receiving all pertinent information, electronic preauthorization requests for health care services, except pharmaceutical services, that are not urgent; **[**and**]**

(4) ON OR BEFORE JANUARY 1, 2015, ESTABLISHMENT, BY EACH PAYOR THAT REQUIRES A STEP THERAPY OR FAIL–FIRST PROTOCOL, OF A

PROCESS FOR A PROVIDER TO OVERRIDE THE STEP THERAPY OR FAIL–FIRST PROTOCOL OF THE PAYOR; AND

[(4)] **(5)** On or before July 1, 2015, utilization by providers of:

(i) The online preauthorization system established by payors; or

(ii) If a national transaction standard has been established and adopted by the health care industry, as determined by the Commission, the provider's practice management, electronic health record, or e–prescribing system.

(d) The benchmarks described in subsections (b) and (c) of this section do not apply to preauthorizations of health care services requested by providers employed by a group model health maintenance organization as defined in § 19–713.6 of this title.

(e) The online preauthorization system described in subsection (c)(3) of this section shall:

(1) Provide real–time notice to providers about preauthorization requests approved in real time; and

(2) Provide notice to providers, within the time frames specified in subsection (c)(3)(ii) and (iii) of this section and in a manner that is able to be tracked by providers, about preauthorization requests not approved in real time.

(f) (1) The Commission shall establish by regulation a process through which a payor or provider may be waived from attaining the benchmarks described in subsections (b) and (c) of this section for extenuating circumstances.

(2) For a provider, the extenuating circumstances may include:

(i) The lack of broadband Internet access;

(ii) Low patient volume; or

(iii) Not making medical referrals or prescribing pharmaceuticals.

(3) For a payor, the extenuating circumstances may include:

(i) Low premium volume; or

(ii) For a group model health maintenance organization, as defined in § 19–713.6 of this title, preauthorizations of health care services requested by providers not employed by the group model health maintenance organization.

1 (g) (1) On or before October 1, 2012, the Commission shall reconvene the
2 multistakeholder workgroup whose collaboration resulted in the 2011 report
3 "Recommendations for Implementing Electronic Prior Authorizations".

4 (2) The workgroup shall:

5 (i) Review the progress to date in attaining the benchmarks
6 described in subsections (b) and (c) of this section; and

7 (ii) Make recommendations to the Commission for adjustments
8 to the benchmark dates.

9 (h) **[**(1) Payors shall report to the Commission:

10 (i) On or before March 1, 2013, on:

11 1. The status of their attainment of the Phase 1 and
12 Phase 2 benchmarks; and

13 2. An outline of their plans for attaining the Phase 3
14 benchmarks; and

15 (ii) On or before December 1, 2013, on their attainment of the
16 Phase 3 benchmarks.

17 (2) The Commission shall specify the criteria payors must use in
18 reporting on their attainment and plans.

19 (i) (1) On or before March 31, 2013, the Commission shall report to the
20 Governor and, in accordance with § 2–1246 of the State Government Article, the
21 General Assembly, on:

22 (i) The progress in attaining the benchmarks for standardizing
23 and automating the process required by payors for preauthorizing health care services;
24 and

25 (ii) Taking into account the recommendations of the
26 multistakeholder workgroup under subsection (g) of this section, any adjustment
27 needed to the Phase 2 or Phase 3 benchmark dates.

28 (2)**]** On or before December 31, 2013, and on or before December 31 in
29 each succeeding year through 2016, the Commission shall report to the Governor and,
30 in accordance with § 2–1246 of the State Government Article, the General Assembly
31 on the attainment of the benchmarks for standardizing and automating the process
32 required by payors for preauthorizing health care services.

[(j)] **(I)** If necessary to attain the benchmarks, the Commission may adopt regulations to:

(1) Adjust the Phase 2 or Phase 3 benchmark dates;

(2) Require payors and providers to comply with the benchmarks; and

(3) Establish penalties for noncompliance.

19–706.

(OOOO) THE PROVISIONS OF § 15–141 OF THE INSURANCE ARTICLE APPLY TO HEALTH MAINTENANCE ORGANIZATIONS.

Article – Insurance

15–141.

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

(2) "STEP THERAPY OR FAIL–FIRST PROTOCOL" MEANS A PROTOCOL ESTABLISHED BY AN INSURER, A NONPROFIT HEALTH SERVICE PLAN, OR A HEALTH MAINTENANCE ORGANIZATION THAT REQUIRES A PRESCRIPTION DRUG OR SEQUENCE OF PRESCRIPTION DRUGS TO BE USED BY AN INSURED OR AN ENROLLEE BEFORE A PRESCRIPTION DRUG ORDERED BY A PRESCRIBER FOR THE INSURED OR THE ENROLLEE IS COVERED.

(3) "STEP THERAPY DRUG" MEANS A PRESCRIPTION DRUG OR SEQUENCE OF PRESCRIPTION DRUGS REQUIRED TO BE USED UNDER A STEP THERAPY OR FAIL–FIRST PROTOCOL.

(B) (1) THIS SECTION APPLIES TO:

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

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

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

(C) IF AN ENTITY SUBJECT TO THIS SECTION IMPOSES A STEP THERAPY OR FAIL–FIRST PROTOCOL ON AN INSURED OR ENROLLEE, THE DURATION OF THE STEP THERAPY OR FAIL–FIRST PROTOCOL MAY NOT EXCEED:

(1) ANY PERIOD AGREED TO BY THE INSURED'S OR ENROLLEE'S PRESCRIBER AND THE ENTITY TO DETERMINE THE CLINICAL EFFECTIVENESS OF THE STEP THERAPY DRUG; OR

(2) 30 DAYS.

(D) AN ENTITY SUBJECT TO THIS SECTION MAY NOT IMPOSE A STEP THERAPY OR FAIL–FIRST PROTOCOL ON AN INSURED OR ENROLLEE IF:

(1) THE STEP THERAPY DRUG HAS NOT BEEN APPROVED BY THE U.S. FOOD AND DRUG ADMINISTRATION FOR THE MEDICAL CONDITION BEING TREATED; OR

(2) A PRESCRIBER DOCUMENTS AND NOTIFIES THE ENTITY THAT A PRESCRIPTION DRUG COVERED BY THE ENTITY:

(I) WAS ORDERED BY THE PRESCRIBER FOR THE INSURED OR ENROLLEE WITHIN THE PAST 365 DAYS; AND

(II) BASED ON THE PROFESSIONAL JUDGMENT OF THE PRESCRIBER, WAS EFFECTIVE IN TREATING THE INSURED'S OR ENROLLEE'S DISEASE OR MEDICAL CONDITION.

(E) THIS SECTION MAY NOT BE CONSTRUED TO REQUIRE COVERAGE FOR A PRESCRIPTION DRUG THAT IS NOT:

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

(2) OTHERWISE REQUIRED BY LAW TO BE COVERED.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect July 1, 2014.