By: Delegates Bromwell, Cullison, Frank, Hubbard, Kach, Kipke, Morhaim, Nathan-Pulliam, Oaks, Reznik, Szeliga, Tarrant, and V. Turner <u>V. Turner, Costa, Donoghue, Elliott, Hammen, Krebs, McDonough,</u> Murphy, Pena-Melnyk, Pendergrass, and Ready

Introduced and read first time: February 7, 2014 Assigned to: Health and Government Operations

Committee Report: Favorable with amendments House action: Adopted Read second time: March 12, 2014

CHAPTER _____

1 AN ACT concerning

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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 $\mathbf{5}$ 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 health maintenance organization; prohibiting the a certain insurer, nonprofit 10 health service plan, or health maintenance organization from imposing a step 11 12 therapy or fail-first protocol on an insured or enrollee under certain 13 circumstances; prohibiting certain provisions of this Act from being construed to 14require certain coverage; repealing certain obsolete provisions of law; defining 15certain terms; making certain provisions of this Act applicable to health 16 maintenance organizations; and generally relating to step therapy or fail-first 17protocols in 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

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.

<u>Underlining</u> indicates amendments to bill.

Strike out indicates matter stricken from the bill by amendment or deleted from the law by amendment.



1	(2009 Replacement Volume and 2013 Supplement)					
$2 \\ 3 \\ 4 \\ 5 \\ 6$	BY adding to Article – Health – General Section 19–706(0000) Annotated Code of Maryland (2009 Replacement Volume and 2013 Supplement)					
7 8 9 10 11	BY adding to Article – Insurance Section 15–141 Annotated Code of Maryland (2011 Replacement Volume and 2013 Supplement)					
$\frac{12}{13}$	SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:					
14	Article – Health – General					
15	19–108.2.					
16	(a) (1) In this section the following words have the meanings indicated.					
17 18	(2) "Health care service" has the meaning stated in § 15–10A–01 of the Insurance Article.					
19	(3) "Payor" means:					
$20 \\ 21 \\ 22 \\ 23$	(i) An insurer or nonprofit health service plan that provides 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;					
$24 \\ 25 \\ 26$	(ii) A health maintenance organization that provides hospital, medical, or surgical benefits to individuals or groups under contracts that are issued or delivered in the State; or					
$\begin{array}{c} 27\\ 28 \end{array}$	(iii) A pharmacy benefits manager that is registered with the Maryland Insurance Commissioner.					
29	(4) "Provider" has the meaning stated in § 19–7A–01 of this title.					
$\frac{30}{31}$	(5) "Step therapy or fail-first protocol" has the meaning stated in § 15–141 of the Insurance Article.					
32 33	(b) In addition to the duties stated elsewhere in this subtitle, the Commission shall work with payors and providers to attain benchmarks for:					

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$rac{1}{2}$	· / -	andardizing] STANDARDIZING and automating the process preauthorizing health care services; AND
$\frac{3}{4}$	(2) OV PROTOCOL.	VERRIDING A PAYOR'S STEP THERAPY OR FAIL-FIRST
5	(c) The bencl	hmarks described in subsection (b) of this section shall include:
$6 \\ 7$	(1) On access for providers to	or before October 1, 2012 ("Phase 1"), establishment of online each payor's:
8 9	(i) and	List of health care services that require preauthorization;
10 11	(ii) preauthorization reque	
$\begin{array}{c} 12\\ 13 \end{array}$	(2) On payor of an online proc	or before March 1, 2013 ("Phase 2"), establishment by each cess for:
$\begin{array}{c} 14 \\ 15 \end{array}$	(i) provider; and	Accepting electronically a preauthorization request from a
16 17 18 19		• that a provider may use to track the request during the ess, whether or not the request is tracked electronically, through
$\begin{array}{c} 20\\ 21 \end{array}$		or before July 1, 2013 ("Phase 3"), establishment by each payor ization system to approve:
$\frac{22}{23}$	(i) pharmaceutical service	In real time, electronic preauthorization requests for es:
$\begin{array}{c} 24 \\ 25 \end{array}$	payor to process the pr	1. For which no additional information is needed by the reauthorization request; and
26		2. That meet the payor's criteria for approval;
27 28 29	(ii) information on reque requests for pharmace	ests not approved in real time, electronic preauthorization
30		1. Are not urgent; and

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1 2. Do not meet the standards for real-time approval $\mathbf{2}$ under item (i) of this item; and 3 (iii) Within 2 business days after receiving all pertinent 4 information, electronic preauthorization requests for health care services, except $\mathbf{5}$ pharmaceutical services, that are not urgent; [and] 6 (4) ON OR BEFORE **JANUARY** JULY 1, 2015, ESTABLISHMENT, BY 7EACH PAYOR THAT REQUIRES A STEP THERAPY OR FAIL-FIRST PROTOCOL, OF A 8 PROCESS FOR A PROVIDER TO OVERRIDE THE STEP THERAPY OR FAIL-FIRST 9 **PROTOCOL OF THE PAYOR; AND** 10 **[**(4)**] (5)** On or before July 1, 2015, utilization by providers of: 11 (i) The online preauthorization system established by payors; 12or 13 If a national transaction standard has been established and (ii) adopted by the health care industry, as determined by the Commission, the provider's 1415practice management, electronic health record, or e-prescribing system. 16 The benchmarks described in subsections (b) and (c) of this section do not (d) 17apply to preauthorizations of health care services requested by providers employed by 18 a group model health maintenance organization as defined in § 19–713.6 of this title. 19The online preauthorization system described in subsection (c)(3) of this (e) section shall: 2021(1)Provide real-time notice to providers about preauthorization 22requests approved in real time; and 23Provide notice to providers, within the time frames specified in (2)24subsection (c)(3)(ii) and (iii) of this section and in a manner that is able to be tracked 25by providers, about preauthorization requests not approved in real time. 26(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 27subsections (b) and (c) of this section for extenuating circumstances. 28

- 29 (2) For a provider, the extenuating circumstances may include:
- 30 (i) The lack of broadband Internet access;
- 31 (ii) Low patient volume; or

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$rac{1}{2}$	pharmaceuticals.	(iii)	Not	making	medical	referrals	or	prescribing
3	(3)	For a	payor,	the extenua	ating circum	stances may	inclu	de:
4		(i)	Low p	remium vol	ume; or			
$5\\6\\7$	defined in § 19–71 by providers not en		this tit	le, preauth	orizations of	f health care	servi	
$8\\9\\10$	(g) (1) multistakeholder "Recommendations	workg	group	whose coll	aboration 1	resulted in	the	econvene the 2011 report
11	(2)	The v	vorkgro	oup shall:				
$\begin{array}{c} 12\\ 13 \end{array}$	described in subse	(i) ctions				e in attainin	ig the	benchmarks
$\begin{array}{c} 14 \\ 15 \end{array}$	to the benchmark	(ii) dates.	Make	recomment	lations to th	ne Commissi	on for	adjustments
16	(h) [(1)	Payor	rs shall	report to th	ne Commissi	on:		
17		(i)	On or	before Mar	ch 1, 2013, c	on:		
$\frac{18}{19}$	Phase 2 benchmar	ks; and	1. d	The status	s of their a	ttainment of	f the 1	Phase 1 and
$\begin{array}{c} 20\\ 21 \end{array}$	benchmarks; and		2.	An outline	of their pl	ans for atta	ining	the Phase 3
22 23	Phase 3 benchmar	(ii) ks.	On or	before Dec	ember 1, 20)13, on their	• attai:	nment of the
$\begin{array}{c} 24 \\ 25 \end{array}$	(2) reporting on their				specify the	e criteria pa	ayors	must use in
26 27 28	(i) (1) Governor and, in General Assembly	accord						report to the Article, the
29 30 31	and automating th and	(i) le proce	_	-	-			tandardizing care services;

$egin{array}{c} 1 \ 2 \end{array}$	(ii) Taking into account the recommendations of the multistakeholder workgroup under subsection (g) of this section, any adjustment
3	needed to the Phase 2 or Phase 3 benchmark dates.
$4 \\ 5 \\ 6 \\ 7 \\ 8$	(2)] On or before December 31, 2013, and on or before December 31 in each succeeding year through 2016, the Commission shall report to the Governor and, in accordance with § 2–1246 of the State Government Article, the General Assembly on the attainment of the benchmarks for standardizing and automating the process required by payors for preauthorizing health care services.
9 10	[(j)] (I) If necessary to attain the benchmarks, the Commission may adopt regulations to:
11	(1) Adjust the Phase 2 or Phase 3 benchmark dates;
12	(2) Require payors and providers to comply with the benchmarks; and
13	(3) Establish penalties for noncompliance.
14	19–706.
$\frac{15}{16}$	(0000) THE PROVISIONS OF § 15–141 OF THE INSURANCE ARTICLE APPLY TO HEALTH MAINTENANCE ORGANIZATIONS.
16	APPLY TO HEALTH MAINTENANCE ORGANIZATIONS.
16 17	APPLY TO HEALTH MAINTENANCE ORGANIZATIONS. Article – Insurance
16 17 18 19	APPLY TO HEALTH MAINTENANCE ORGANIZATIONS. Article – Insurance 15–141. (A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE
 16 17 18 19 20 21 22 	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
 16 17 18 19 20 21 22 23 	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
 16 17 18 19 20 21 22 	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
 16 17 18 19 20 21 22 23 24 	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
 16 17 18 19 20 21 22 23 24 25 	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
 16 17 18 19 20 21 22 23 24 25 26 27 28 	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
 16 17 18 19 20 21 22 23 24 25 26 27 	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

30 (4) "SUPPORTING MEDICAL INFORMATION" MEANS:

1	(I) <u>A PAID CLAIM FROM AN ENTITY SUBJECT TO THIS</u>
2	SECTION FOR AN INSURED OR AN ENROLLEE;
3	(II) A PHARMACY RECORD THAT DOCUMENTS THAT A
4	PRESCRIPTION HAS BEEN FILLED AND DELIVERED TO AN INSURED OR AN
5	ENROLLEE, OR A REPRESENTATIVE OF AN INSURED OR AN ENROLLEE; OR
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6	(III) OTHER INFORMATION MUTUALLY AGREED ON BY AN
7	ENTITY SUBJECT TO THIS SECTION AND THE PRESCRIBER OF AN INSURED OR AN
8	ENROLLEE.
0	ENROLLEE.
9	(B) (1) THIS SECTION APPLIES TO:
9	(b) (1) THIS SECTION AFFLIES 10.
10	(I) INSURERS AND NONPROFIT HEALTH SERVICE PLANS
10	THAT PROVIDE HOSPITAL, MEDICAL, OR SURGICAL BENEFITS TO INDIVIDUALS
12	OR GROUPS ON AN EXPENSE-INCURRED BASIS UNDER HEALTH INSURANCE
13	POLICIES OR CONTRACTS THAT ARE ISSUED OR DELIVERED IN THE STATE; AND
14	(II) HEALTH MAINTENANCE ORGANIZATIONS THAT PROVIDE
15	HOSPITAL, MEDICAL, OR SURGICAL BENEFITS TO INDIVIDUALS OR GROUPS
16	UNDER CONTRACTS THAT ARE ISSUED OR DELIVERED IN THE STATE.
17	(2) AN INSURER, A NONPROFIT HEALTH SERVICE PLAN, OR A
18	HEALTH MAINTENANCE ORGANIZATION THAT PROVIDES COVERAGE FOR
19	PRESCRIPTION DRUGS THROUGH A PHARMACY BENEFITS MANAGER IS SUBJECT
20	TO THE REQUIREMENTS OF THIS SECTION.
21	(C) I F AN ENTITY SUBJECT TO THIS SECTION IMPOSES A STEP THERAPY
22	OR FAIL-FIRST PROTOCOL ON AN INSURED OR ENROLLEE, THE DURATION OF
23	THE STEP THERAPY OR FAIL-FIRST PROTOCOL MAY NOT EXCEED:
24	(1) ANY PERIOD AGREED TO BY THE INSURED'S OR ENROLLEE'S
25	PRESCRIBER AND THE ENTITY TO DETERMINE THE CLINICAL EFFECTIVENESS
26	OF THE STEP THERAPY DRUG; OR
-	
27	(2) 30 DAYS.
28	(D) (C) AN ENTITY SUBJECT TO THIS SECTION MAY NOT IMPOSE A
29	STEP THERAPY OR FAIL-FIRST PROTOCOL ON AN INSURED OR ENROLLEE IF:
-	
30	(1) THE STEP THERAPY DRUG HAS NOT BEEN APPROVED BY THE
31	U.S. FOOD AND DRUG ADMINISTRATION FOR THE MEDICAL CONDITION BEING
32	TREATED; OR
04	11111111/ VI

1(2) A PRESCRIBER DOCUMENTS AND NOTHFIESPROVIDES2SUPPORTING MEDICAL INFORMATION TOTHE ENTITY THAT A PRESCRIPTION3DRUG COVERED BY THE ENTITY:

4 (I) WAS ORDERED BY THE <u>A</u> PRESCRIBER FOR THE 5 INSURED OR ENROLLEE WITHIN THE PAST 365 <u>180</u> DAYS; AND

6 (II) BASED ON THE PROFESSIONAL JUDGMENT OF THE 7 PRESCRIBER, WAS EFFECTIVE IN TREATING THE INSURED'S OR ENROLLEE'S 8 DISEASE OR MEDICAL CONDITION.

9 (E) (D) THIS SECTION MAY NOT BE CONSTRUED TO REQUIRE 10 COVERAGE FOR A PRESCRIPTION DRUG THAT IS NOT:

11(1) COVERED BY THE POLICY OR CONTRACT OF AN ENTITY12SUBJECT TO THIS SECTION; OR

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(2) OTHERWISE REQUIRED BY LAW TO BE COVERED.

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

Approved:

Governor.

Speaker of the House of Delegates.

President of the Senate.

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