SENATE BILL 622

C3 4lr1975 CF HB 1233

By: Senator Middleton

Introduced and read first time: January 30, 2014

Assigned to: Finance

Committee Report: Favorable with amendments

Senate action: Adopted

Read second time: March 11, 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 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 a certain insurer, nonprofit 11 health service plan, or health maintenance organization from imposing a step 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 14 require certain coverage; repealing certain obsolete provisions of law; defining certain terms; making certain provisions of this Act applicable to health 15 16 maintenance organizations; and generally relating to step therapy or fail-first 17 protocols 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
- 22 (2009 Replacement Volume and 2013 Supplement)

23 BY adding to

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.



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1 2 3 4	Article – Health – General Section 19–706(0000) Annotated Code of Maryland (2009 Replacement Volume and 2013 Supplement)
5 6 7 8 9	BY adding to Article – Insurance Section 15–141 Annotated Code of Maryland (2011 Replacement Volume and 2013 Supplement)
10 11	SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:
12	Article - Health - General
13	19–108.2.
14	(a) (1) In this section the following words have the meanings indicated.
15 16	(2) "Health care service" has the meaning stated in § 15–10A–01 of the Insurance Article.
17	(3) "Payor" means:
18 19 20 21	(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;
22 23 24	(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
$\begin{array}{c} 25 \\ 26 \end{array}$	(iii) A pharmacy benefits manager that is registered with the Maryland Insurance Commissioner.
27	(4) "Provider" has the meaning stated in § 19–7A–01 of this title.
28 29	(5) "STEP THERAPY OR FAIL-FIRST PROTOCOL" HAS THE MEANING STATED IN § 15–141 OF THE INSURANCE ARTICLE.
30 31	(b) In addition to the duties stated elsewhere in this subtitle, the Commission shall work with payors and providers to attain benchmarks for:

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

1 2	PROTOCOL	(2)	OVE	RRIDING	A	PAYOR'S	S STEP	THERAP	Y OR	FAIL-	FIRST
3	(c)	The b	enchm	arks desc	ribe	d in subs	ection (b) of this se	ection s	hall incl	ude:
4 5	access for pr	(1) rovidei				per 1, 201	12 ("Pha	se 1"), est	ablishr	nent of	online
6 7	and		(i)	List of	healt	th care s	services	that requi	ire pre	authoriz	ation;
8 9	preauthoriz	ation 1	(ii) request	•	riteri	ia for	making	g a det	termina	ation (on a
10 11	payor of an	(2) online			Marc	eh 1, 201	13 ("Pha	se 2"), es	tablish	ment by	[,] each
12 13	provider; an	nd	(i)	Acceptin	ıg el	ectronica	lly a pr	eauthoriza	ation re	equest f	rom a
14 15 16 17	identification preauthorize a call center	ation p	process,	hat a pr	ovid	er may	use to 1		reques	st durin	g the
18 19	of an online	(3) preau), establis	hment	by each	payor
20 21	pharmaceut	cical se	(i) ervices:	In real	tin	ne, elect	cronic p	reauthoriz	zation	request	s for
22 23	payor to pro	ocess th	ne prea					l informat	tion is	needed l	by the
24				2. T	hat r	meet the	payor's c	riteria for	approv	al;	
25 26 27	information requests for		_	s not ap	prov	ved in r	•	fter rece e, electro	_	-	
28				1. A	re no	ot urgent;	and				
29 30	under item	(i) of tl	nis item		o no	ot meet	the stan	dards for	real-t	time ap	proval

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(3)

1 2 3	information, elect pharmaceutical se			requests for		_	-
4 5 6 7	(4) EACH PAYOR THA PROCESS FOR A PROTOCOL OF TH	T REG	DER TO OVERRI	HERAPY OR	FAIL-FIRST	PROT	OCOL, OF A
8	[(4)]	(5)	On or before July	1, 2015, util	ization by pr	ovider	s of:
9 10	or	(i)	The online preat	ıthorization	system esta	blished	l by payors;
11 12 13	adopted by the heapractice management		•	termined by	the Commiss	sion, th	
14 15 16	(d) The bapply to preauthor a group model hear	rizatior		ervices reque	ested by prov	viders e	employed by
17 18	(e) The o	nline j	reauthorization s	ystem descri	ibed in subse	ection ((c)(3) of this
19 20	(1) requests approved		e real–time not time; and	cice to prov	viders about	prea	uthorization
21 22 23	(2) subsection (c)(3)(ii) by providers, about	and (and in a ma	nner that is	able to	-
24 25 26	(f) (1) which a payor or p subsections (b) and	rovide		rom attainin	ng the benchr	-	_
27	(2)	For a	provider, the exte	nuating circı	ımstances m	ay incl	ude:
28		(i)	The lack of broad	band Interne	et access;		
29		(ii)	Low patient volu	me; or			
30 31	pharmaceuticals.	(iii)	Not making	medical	referrals	or	prescribing

For a payor, the extenuating circumstances may include:

1		(i)	Low premium volume; or
2 3 4	•		For a group model health maintenance organization, as this title, preauthorizations of health care services requested by the group model health maintenance organization.
5 6 7		work	r before October 1, 2012, the Commission shall reconvene the group whose collaboration resulted in the 2011 report applementing Electronic Prior Authorizations".
8	(2)	The v	vorkgroup shall:
9 10	described in subse	(i) ections	Review the progress to date in attaining the benchmarks (b) and (c) of this section; and
11 12	to the benchmark	(ii) dates.	Make recommendations to the Commission for adjustments
13	(h) [(1)	Payor	rs shall report to the Commission:
14		(i)	On or before March 1, 2013, on:
15 16	Phase 2 benchmar	·ks; an	1. The status of their attainment of the Phase 1 and d
17 18	benchmarks; and		2. An outline of their plans for attaining the Phase 3
19 20	Phase 3 benchmar	(ii) ·ks.	On or before December 1, 2013, on their attainment of the
21 22	(2) reporting on their		Commission shall specify the criteria payors must use in ment and plans.
23 24 25	(i) (1) Governor and, in General Assembly	accor	r before March 31, 2013, the Commission shall report to the dance with § 2–1246 of the State Government Article, the
26 27 28	and automating thand	(i) ne proc	The progress in attaining the benchmarks for standardizing ess required by payors for preauthorizing health care services;
29 30 31			Taking into account the recommendations of the roup under subsection (g) of this section, any adjustment Phase 3 benchmark dates.

1 2 3 4 5	in accordance wit	On or before December 31, 2013, and on or before December 31 in ear through 2016, the Commission shall report to the Governor and, h § 2–1246 of the State Government Article, the General Assembly t of the benchmarks for standardizing and automating the process s for preauthorizing health care services.
6 7	[(j)] (I) regulations to:	If necessary to attain the benchmarks, the Commission may adopt
8	(1)	Adjust the Phase 2 or Phase 3 benchmark dates;
9	(2)	Require payors and providers to comply with the benchmarks; and
10	(3)	Establish penalties for noncompliance.
11	19–706.	
12 13	(0000) APPLY TO HEALT	THE PROVISIONS OF § 15–141 OF THE INSURANCE ARTICLE TH MAINTENANCE ORGANIZATIONS.
14		Article – Insurance
15	15–141.	
16 17	(A) (1) MEANINGS INDIC	IN THIS SECTION THE FOLLOWING WORDS HAVE THE CATED.
18 19 20 21 22 23	PLAN, OR A F PRESCRIPTION I AN INSURED OR	"STEP THERAPY OR FAIL-FIRST PROTOCOL" MEANS A ABLISHED BY AN INSURER, A NONPROFIT HEALTH SERVICE HEALTH MAINTENANCE ORGANIZATION THAT REQUIRES A DRUG OR SEQUENCE OF PRESCRIPTION DRUGS TO BE USED BY AN ENROLLEE BEFORE A PRESCRIPTION DRUG ORDERED BY A R THE INSURED OR THE ENROLLEE IS COVERED.
242526	*	"STEP THERAPY DRUG" MEANS A PRESCRIPTION DRUG OR PRESCRIPTION DRUGS REQUIRED TO BE USED UNDER A STEP IL-FIRST PROTOCOL.
27	(4)	"CUPPOPEING MEDICAL INCODMATION?" MEANG.
28	<u>(4)</u>	"SUPPORTING MEDICAL INFORMATION" MEANS: (I) A PAID CLAIM FROM AN ENTITY SUBJECT TO THIS

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

$\frac{1}{2}$	(I) WAS ORDERED BY THE \underline{A} PRESCRIBER FOR THE INSURED OR ENROLLEE WITHIN THE PAST $\underline{365}$ $\underline{180}$ DAYS; AND
3 4 5	(II) BASED ON THE PROFESSIONAL JUDGMENT OF THE PRESCRIBER, WAS EFFECTIVE IN TREATING THE INSURED'S OR ENROLLEE'S DISEASE OR MEDICAL CONDITION.
6 7	(E) (D) THIS SECTION MAY NOT BE CONSTRUED TO REQUIRE COVERAGE FOR A PRESCRIPTION DRUG THAT IS NOT:
8 9	(1) COVERED BY THE POLICY OR CONTRACT OF AN ENTITY SUBJECT TO THIS SECTION; OR
10	(2) OTHERWISE REQUIRED BY LAW TO BE COVERED.
11 12	SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect July 1, 2014.
	Approved:
	Governor.
	President of the Senate.
	Speaker of the House of Delegates.