

SENATE BILL 347

J2

(5lr1581)

ENROLLED BILL

— Education, Health, and Environmental Affairs/Health and Government Operations —

Introduced by **Senators Pugh, Middleton, Bates, Feldman, Madaleno, Montgomery, Nathan-Pulliam, Salling, Waugh, and Young**

Read and Examined by Proofreaders:

Proofreader.

Proofreader.

Sealed with the Great Seal and presented to the Governor, for his approval this

_____ day of _____ at _____ o'clock, _____ M.

President.

CHAPTER _____

1 AN ACT concerning

2 **Health Occupations – Prescriber-Pharmacist Agreements and Therapy**
3 **Management Contracts**

4 FOR the purpose of authorizing certain ~~dentists~~, physicians, podiatrists, ~~nurse-midwives,~~
5 ~~and nurse-practitioners~~ and advanced practice nurses to enter into certain
6 agreements; requiring certain prescribers who wish to enter certain therapy
7 management contracts to have certain agreements; requiring certain prescribers and
8 certain pharmacists to submit to certain health occupations boards certain
9 documents; authorizing certain pharmacists to enter into certain agreements and
10 certain contracts under certain circumstances; prohibiting certain pharmacists from
11 employing or providing certain incentives to certain prescribers for certain purposes;
12 providing that a ~~certain~~ protocol by a licensed physician and licensed pharmacist
13 may authorize the initiation of certain drug therapy; ~~providing that certain protocols~~
14 ~~may authorize certain drug substitutions; repealing a certain prohibition against~~

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.

Underlining indicates amendments to bill.

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

Italics indicate opposite chamber / conference committee amendments.



~~certain drug substitutions except under certain circumstances~~; repealing a provision of law that provides for the termination of a therapy management contract after a certain time period unless there is a certain renewal; specifying that certain contracts apply only to conditions agreed to by certain prescribers; requiring certain contracts to include certain provisions; authorizing the Board of Pharmacy to assess certain fees for certain purposes; requiring certain prescribers to maintain certain records in a certain manner; requiring certain health occupations boards to jointly adopt certain regulations in consultation with certain other health occupations boards; requiring the regulations to include certain provisions; defining certain terms; making certain stylistic changes; and generally relating to prescriber–pharmacist agreements and therapy management contracts.

BY repealing and reenacting, with amendments,

Article – Health Occupations

Section 12–6A–01, 12–6A–03 through 12–6A–08, and 12–6A–10

Annotated Code of Maryland

(2014 Replacement Volume)

BY repealing and reenacting, without amendments,

Article – Health Occupations

Section 12–6A–02

Annotated Code of Maryland

(2014 Replacement Volume)

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

Article – Health Occupations

12–6A–01.

(a) In this subtitle the following words have the meanings indicated.

(B) “AUTHORIZED PRESCRIBER” MEANS A ~~LICENSED DENTIST, LICENSED PHYSICIAN, LICENSED PODIATRIST, CERTIFIED NURSE MIDWIFE TO THE EXTENT AUTHORIZED UNDER § 8-601 OF THIS ARTICLE, OR CERTIFIED NURSE PRACTITIONER TO THE EXTENT AUTHORIZED~~ OR CERTIFIED ADVANCED PRACTICE NURSE WITH PRESCRIPTIVE AUTHORITY UNDER § 8-508 OF THIS ARTICLE.

[(b)] (C) “Group model health maintenance organization” has the meaning stated in § 19–713.6 of the Health – General Article.

[(c)] (D) “Health maintenance organization” has the meaning stated in § 19–701(g) of the Health – General Article.

1 [(d) (E) (1) “Institutional facility” means a facility other than a nursing
2 home whose primary purpose is to provide a physical environment for patients to obtain
3 inpatient or emergency care.

4 (2) “Institutional facility” does not include an urgent care facility that is
5 not part of a facility.

6 [(e) “Licensed physician” means an individual who is licensed to practice medicine
7 under Title 14 of this article.]

8 (f) [“Physician–pharmacist agreement”] **“PRESCRIBER–PHARMACIST**
9 **AGREEMENT”** means an agreement between [a licensed physician] **AN AUTHORIZED**
10 **PRESCRIBER** and a licensed pharmacist that is disease–state specific and specifies the
11 protocols that may be used.

12 (g) “Protocol” means a course of treatment predetermined by the [licensed
13 physician] **AUTHORIZED PRESCRIBER** and licensed pharmacist according to generally
14 accepted medical practice for the proper completion of a particular therapeutic or diagnostic
15 intervention.

16 (h) [(1)] “Therapy management contract” means a voluntary, written
17 arrangement that is [disease–state]:

18 (1) **DISEASE–STATE** specific [signed];

19 (2) **SIGNED** by [each party to the arrangement between]:

20 (i) One licensed pharmacist and the licensed pharmacist’s
21 designated alternate licensed pharmacists;

22 (ii) One [licensed physician] **AUTHORIZED PRESCRIBER** and
23 alternate designated [licensed physicians] **AUTHORIZED PRESCRIBERS** involved directly
24 in patient care; and

25 (iii) One patient receiving care from [a licensed physician] **AN**
26 **AUTHORIZED PRESCRIBER** and a licensed pharmacist pursuant to a
27 [physician–pharmacist] **PRESCRIBER–PHARMACIST** agreement and protocol under this
28 subtitle[.]; **AND**

29 [(2)] (3) [A therapy management contract shall be related] **RELATED** to
30 treatment using drug therapy, laboratory tests, or medical devices, under defined
31 conditions or limitations for the purpose of improving patient outcomes.

32 12–6A–02.

1 A therapy management contract is not required for the management of patients in
2 an institutional facility or in a group model health maintenance organization.

3 12-6A-03.

4 (a) [A licensed physician] **AN AUTHORIZED PRESCRIBER** and a licensed
5 pharmacist who wish to enter into therapy management contracts shall have a
6 [physician-pharmacist] **PRESCRIBER-PHARMACIST** agreement.

7 (b) (1) [A licensed physician] **AN AUTHORIZED PRESCRIBER** who has
8 entered into a [physician-pharmacist] **PRESCRIBER-PHARMACIST** agreement shall
9 submit to the [Board of Physicians] **HEALTH OCCUPATIONS BOARD THAT REGULATES**
10 **THE AUTHORIZED PRESCRIBER** a copy of the [physician-pharmacist]
11 **PRESCRIBER-PHARMACIST** agreement and any subsequent modifications made to the
12 [physician-pharmacist] **PRESCRIBER-PHARMACIST** agreement or the protocols specified
13 in the [physician-pharmacist] **PRESCRIBER-PHARMACIST** agreement.

14 (2) A licensed pharmacist who has entered into a [physician-pharmacist]
15 **PRESCRIBER-PHARMACIST** agreement shall submit to the Board of Pharmacy a copy of
16 the [physician-pharmacist] **PRESCRIBER-PHARMACIST** agreement and any subsequent
17 modifications made to the [physician-pharmacist] **PRESCRIBER-PHARMACIST**
18 agreement or the protocols specified in the [physician-pharmacist]
19 **PRESCRIBER-PHARMACIST** agreement.

20 12-6A-04.

21 A pharmacist is authorized to enter into a [physician-pharmacist]
22 **PRESCRIBER-PHARMACIST** agreement if the pharmacist:

23 (1) Is a licensed pharmacist;

24 (2) Has a Doctor of Pharmacy Degree or equivalent training as established
25 in regulations adopted under this subtitle;

26 (3) Is approved by the Board to enter into a [physician-pharmacist]
27 **PRESCRIBER-PHARMACIST** agreement with [a licensed physician] **AN AUTHORIZED**
28 **PRESCRIBER** in accordance with this subtitle; and

29 (4) Meets the requirements that are established by regulations adopted
30 under this subtitle.

31 12-6A-05.

1 (a) Subject to the regulations adopted under this subtitle, a licensed pharmacist
2 may enter into a therapy management contract initiated by [a licensed physician] AN
3 **AUTHORIZED PRESCRIBER.**

4 (b) A licensed pharmacist may not employ or provide economic incentives to [a
5 licensed physician] AN **AUTHORIZED PRESCRIBER** for the purpose of entering into a
6 [physician–pharmacist] **PRESCRIBER–PHARMACIST** agreement or a therapy
7 management contract.

8 12–6A–06.

9 (a) A protocol under this subtitle:

10 (1) May authorize:

11 **(I) FOR PROTOCOLS BY A LICENSED PHYSICIAN AND LICENSED**
12 **PHARMACIST, THE INITIATION OF DRUG THERAPY UNDER WRITTEN, DISEASE–STATE**
13 **SPECIFIC PROTOCOLS;**

14 ~~(i)~~ **(II)** The ~~INITIATION,~~ modification, continuation, and
15 discontinuation of drug therapy under written, disease–state specific protocols;

16 ~~(ii)~~ **(III)** The ordering of laboratory tests; and

17 ~~(iii)~~ **(IV)** Other patient care management measures related to
18 monitoring or improving the outcomes of drug or device therapy; and

19 (2) May not authorize acts that exceed the scope of practice of the parties
20 to the therapy management contract.

21 (b) A protocol [~~shall prohibit~~] ~~MAY AUTHORIZE~~ the substitution of a chemically
22 dissimilar drug product by the pharmacist for the product prescribed by the [~~physician~~
23 **AUTHORIZED PRESCRIBER**, unless permitted in the therapy management contract]
24 ~~AUTHORIZED PRESCRIBER.~~

25 12–6A–07.

26 (a) A therapy management contract shall apply only to conditions for which
27 protocols have been agreed to by [a licensed physician] AN **AUTHORIZED PRESCRIBER**
28 and a licensed pharmacist in accordance with the regulations adopted under this subtitle.

29 [(b) A therapy management contract shall terminate 1 year from the date of its
30 signing, unless renewed by the licensed physician, licensed pharmacist, and patient.]

31 [(c)] **(B)** A therapy management contract shall include:

1 (1) A statement that none of the parties involved in the therapy
2 management contract have been coerced, given economic incentives, excluding normal
3 reimbursement for services rendered, or involuntarily required to participate;

4 (2) Notice to the patient indicating [how]:

5 (I) THAT THE PATIENT MAY TERMINATE THE THERAPY
6 MANAGEMENT CONTRACT AT ANY TIME; AND

7 (II) THE PROCEDURE BY WHICH the patient may terminate the
8 therapy management contract;

9 (3) A procedure for periodic review by the [physician] AUTHORIZED
10 PRESCRIBER, of the drugs modified pursuant to the agreement or changed with the
11 consent of the [physician] AUTHORIZED PRESCRIBER; and

12 (4) Reference to a protocol, which will be provided to the patient [upon] ON
13 request.

14 [(d)] (C) Any party to the therapy management contract may terminate the
15 contract at any time.

16 [(e)] (D) The Board [of Pharmacy] may assess a fee, as established in regulation,
17 for approval of a pharmacist to enter into a [physician-pharmacist]
18 PRESCRIBER-PHARMACIST agreement.

19 12-6A-08.

20 (a) The [physician] AUTHORIZED PRESCRIBER shall maintain complete patient
21 records with respect to the therapy management contract.

22 (b) The [licensed physician's] AUTHORIZED PRESCRIBER'S patient record shall
23 be fully updated in writing by the licensed pharmacist in a timely manner, as provided in
24 the [physician-pharmacist] PRESCRIBER-PHARMACIST agreement.

25 12-6A-10.

26 ~~(a) Subject to subsection (b) of this section, the Board [of Pharmacy], together~~
27 ~~with the Board of Physicians AND THE BOARD OF NURSING, shall jointly develop and~~
28 ~~adopt regulations to implement the provisions of this subtitle.~~

29 ~~(A) SUBJECT TO SUBSECTION (B) OF THIS SECTION, THE BOARD SHALL~~
30 ~~JOINTLY DEVELOP AND ADOPT REGULATIONS TO IMPLEMENT THE PROVISIONS OF~~
31 ~~THIS SUBTITLE WITH THE BOARD OF PHYSICIANS AND IN CONSULTATION WITH THE~~

~~1 BOARD OF PODIATRIC MEDICAL EXAMINERS, THE BOARD OF DENTAL EXAMINERS,
2 AND THE BOARD OF NURSING.~~

3 (A) SUBJECT TO SUBSECTION (B) OF THIS SECTION, THE BOARD, TOGETHER
4 WITH THE BOARD OF PHYSICIANS AND IN CONSULTATION WITH THE BOARD OF
5 PODIATRIC MEDICAL EXAMINERS AND THE BOARD OF NURSING, SHALL JOINTLY
6 DEVELOP AND ADOPT REGULATIONS TO IMPLEMENT THE PROVISIONS OF THIS
7 SUBTITLE.

8 (b) The regulations adopted under subsection (a) of this section:

9 (1) Shall include provisions that:

10 (i) Define the criteria for [physician–pharmacist]
11 **PRESCRIBER–PHARMACIST** agreements; and

12 (ii) Establish guidelines concerning the use of protocols, including
13 communication, documentation, and other relevant factors; and

14 (2) May not require [the Board of Physicians or the Board of Pharmacy] A
15 **HEALTH OCCUPATIONS BOARD** to approve a [physician–pharmacist]
16 **PRESCRIBER–PHARMACIST** agreement or the protocols specified in a
17 [physician–pharmacist] **PRESCRIBER–PHARMACIST** agreement.

18 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
19 October 1, 2015.

Approved:

Governor.

President of the Senate.

Speaker of the House of Delegates.