

HOUSE BILL 716

J2

5lr0559
CF SB 347

By: **Delegates Pena–Melnik, Krebs, Barron, Bromwell, Cullison, Hayes, Hill, and Oaks**

Introduced and read first time: February 12, 2015

Assigned to: Health and Government Operations

Committee Report: Favorable with amendments

House action: Adopted

Read second time: March 20, 2015

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~~
15 ~~certain drug substitutions except under certain circumstances;~~ repealing a provision
16 of law that provides for the termination of a therapy management contract after a
17 certain time period unless there is a certain renewal; specifying that certain
18 contracts apply only to conditions agreed to by certain prescribers; requiring certain
19 contracts to include certain provisions; authorizing the Board of Pharmacy to assess
20 certain fees for certain purposes; requiring certain prescribers to maintain certain
21 records in a certain manner; requiring certain health occupations boards to jointly
22 adopt certain regulations in consultation with certain other health occupations
23 boards; requiring the regulations to include certain provisions; defining certain

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.



1 terms; making certain stylistic changes; and generally relating to
2 prescriber–pharmacist agreements and therapy management contracts.

3 BY repealing and reenacting, with amendments,
4 Article – Health Occupations
5 Section 12–6A–01, 12–6A–03 through 12–6A–08, and 12–6A–10
6 Annotated Code of Maryland
7 (2014 Replacement Volume)

8 BY repealing and reenacting, without amendments,
9 Article – Health Occupations
10 Section 12–6A–02
11 Annotated Code of Maryland
12 (2014 Replacement Volume)

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

15 **Article – Health Occupations**

16 12–6A–01.

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

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

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

25 [(c)] (D) “Health maintenance organization” has the meaning stated in §
26 19–701(g) of the Health – General Article.

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

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

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

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

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

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

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

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

13 (i) One licensed pharmacist and the licensed pharmacist’s
14 designated alternate licensed pharmacists;

15 (ii) One [licensed physician] **AUTHORIZED PRESCRIBER** and
16 alternate designated [licensed physicians] **AUTHORIZED PRESCRIBERS** involved directly
17 in patient care; and

18 (iii) One patient receiving care from [a licensed physician] **AN**
19 **AUTHORIZED PRESCRIBER** and a licensed pharmacist pursuant to a
20 [physician–pharmacist] **PRESCRIBER–PHARMACIST** agreement and protocol under this
21 subtitle[.]; **AND**

22 [(2)] (3) [A therapy management contract shall be related] **RELATED** to
23 treatment using drug therapy, laboratory tests, or medical devices, under defined
24 conditions or limitations for the purpose of improving patient outcomes.

25 12–6A–02.

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

28 12–6A–03.

29 (a) [A licensed physician] **AN AUTHORIZED PRESCRIBER** and a licensed
30 pharmacist who wish to enter into therapy management contracts shall have a
31 [physician–pharmacist] **PRESCRIBER–PHARMACIST** agreement.

1 (b) (1) [A licensed physician] **AN AUTHORIZED PRESCRIBER** who has
2 entered into a [physician–pharmacist] **PRESCRIBER–PHARMACIST** agreement shall
3 submit to the [Board of Physicians] **HEALTH OCCUPATIONS BOARD THAT REGULATES**
4 **THE AUTHORIZED PRESCRIBER** a copy of the [physician–pharmacist]
5 **PRESCRIBER–PHARMACIST** agreement and any subsequent modifications made to the
6 [physician–pharmacist] **PRESCRIBER–PHARMACIST** agreement or the protocols specified
7 in the [physician–pharmacist] **PRESCRIBER–PHARMACIST** agreement.

8 (2) A licensed pharmacist who has entered into a [physician–pharmacist]
9 **PRESCRIBER–PHARMACIST** agreement shall submit to the Board of Pharmacy a copy of
10 the [physician–pharmacist] **PRESCRIBER–PHARMACIST** agreement and any subsequent
11 modifications made to the [physician–pharmacist] **PRESCRIBER–PHARMACIST**
12 agreement or the protocols specified in the [physician–pharmacist]
13 **PRESCRIBER–PHARMACIST** agreement.

14 12–6A–04.

15 A pharmacist is authorized to enter into a [physician–pharmacist]
16 **PRESCRIBER–PHARMACIST** agreement if the pharmacist:

17 (1) Is a licensed pharmacist;

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

20 (3) Is approved by the Board to enter into a [physician–pharmacist]
21 **PRESCRIBER–PHARMACIST** agreement with [a licensed physician] **AN AUTHORIZED**
22 **PRESCRIBER** in accordance with this subtitle; and

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

25 12–6A–05.

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

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

33 12–6A–06.

1 (a) A protocol under this subtitle:

2 (1) May authorize:

3 **(I) FOR PROTOCOLS BY A LICENSED PHYSICIAN AND LICENSED**
 4 **PHARMACIST, THE INITIATION OF DRUG THERAPY UNDER WRITTEN, DISEASE-STATE**
 5 **SPECIFIC PROTOCOLS;**

6 ~~(ii)~~ **(II)** The ~~INITIATION,~~ modification, continuation, and
 7 discontinuation of drug therapy under written, disease-state specific protocols;

8 ~~(iii)~~ **(III)** The ordering of laboratory tests; and

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

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

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

17 12-6A-07.

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

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

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

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

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

28 **(I) THAT THE PATIENT MAY TERMINATE THE THERAPY**
 29 **MANAGEMENT CONTRACT AT ANY TIME; AND**

1 **(II) THE PROCEDURE BY WHICH** the patient may terminate the
2 therapy management contract;

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

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

8 **[(d)] (C)** Any party to the therapy management contract may terminate the
9 contract at any time.

10 **[(e)] (D)** The Board [of Pharmacy] may assess a fee, as established in regulation,
11 for approval of a pharmacist to enter into a [physician–pharmacist]
12 **PRESCRIBER–PHARMACIST** agreement.

13 12–6A–08.

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

16 (b) The [licensed physician’s] **AUTHORIZED PRESCRIBER’S** patient record shall
17 be fully updated in writing by the licensed pharmacist in a timely manner, as provided in
18 the [physician–pharmacist] **PRESCRIBER–PHARMACIST** agreement.

19 12–6A–10.

20 (a) Subject to subsection (b) of this section, the Board [of Pharmacy], together
21 with the Board of Physicians **AND IN CONSULTATION WITH THE BOARD OF PODIATRIC**
22 **MEDICAL EXAMINERS AND THE BOARD OF NURSING**, shall jointly develop and adopt
23 regulations to implement the provisions of this subtitle.

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

25 (1) Shall include provisions that:

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

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

30 (2) May not require [the Board of Physicians or the Board of Pharmacy] **A**
31 **HEALTH OCCUPATIONS BOARD** to approve a [physician–pharmacist]

1 ~~PRESCRIBER-PHARMACIST~~ agreement or the protocols specified in a
2 ~~[physician-pharmacist]~~ ~~PRESCRIBER-PHARMACIST~~ agreement.

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

Approved:

Governor.

Speaker of the House of Delegates.

President of the Senate.