

# HOUSE BILL 716

J2

5l0559  
CF SB 347

---

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

Introduced and read first time: February 12, 2015

Assigned to: Health and Government Operations

---

## A BILL ENTITLED

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 to enter into certain agreements; requiring certain  
6 prescribers who wish to enter certain therapy management contracts to have certain  
7 agreements; requiring certain prescribers and certain pharmacists to submit to  
8 certain health occupations boards certain documents; authorizing certain  
9 pharmacists to enter into certain agreements and certain contracts under certain  
10 circumstances; prohibiting certain pharmacists from employing or providing certain  
11 incentives to certain prescribers for certain purposes; providing that a certain  
12 protocol may authorize the initiation of certain drug therapy; providing that certain  
13 protocols may authorize certain drug substitutions; repealing a certain prohibition  
14 against certain drug substitutions except under certain circumstances; repealing a  
15 provision of law that provides for the termination of a therapy management contract  
16 after a certain time period unless there is a certain renewal; specifying that certain  
17 contracts apply only to conditions agreed to by certain prescribers; requiring certain  
18 contracts to include certain provisions; authorizing the Board of Pharmacy to assess  
19 certain fees for certain purposes; requiring certain prescribers to maintain certain  
20 records in a certain manner; requiring certain health occupations boards to jointly  
21 adopt certain regulations; requiring the regulations to include certain provisions;  
22 defining certain terms; making certain stylistic changes; and generally relating to  
23 prescriber–pharmacist agreements and therapy management contracts.

24 BY repealing and reenacting, with amendments,  
25 Article – Health Occupations  
26 Section 12–6A–01, 12–6A–03 through 12–6A–08, and 12–6A–10  
27 Annotated Code of Maryland  
28 (2014 Replacement Volume)

---

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 BY repealing and reenacting, without amendments,  
2 Article – Health Occupations  
3 Section 12–6A–02  
4 Annotated Code of Maryland  
5 (2014 Replacement Volume)

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

8 **Article – Health Occupations**

9 12–6A–01.

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

11 **(B) “AUTHORIZED PRESCRIBER” MEANS A LICENSED DENTIST, LICENSED**  
12 **PHYSICIAN, LICENSED PODIATRIST, CERTIFIED NURSE MIDWIFE TO THE EXTENT**  
13 **AUTHORIZED UNDER § 8–601 OF THIS ARTICLE, OR CERTIFIED NURSE**  
14 **PRACTITIONER TO THE EXTENT AUTHORIZED UNDER § 8–508 OF THIS ARTICLE.**

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

17 **[(c) (D)** “Health maintenance organization” has the meaning stated in §  
18 19–701(g) of the Health – General Article.

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

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

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

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

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

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

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

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

5 (i) One licensed pharmacist and the licensed pharmacist’s  
6 designated alternate licensed pharmacists;

7 (ii) One [licensed physician] **AUTHORIZED PRESCRIBER** and  
8 alternate designated [licensed physicians] **AUTHORIZED PRESCRIBERS** involved directly  
9 in patient care; and

10 (iii) One patient receiving care from [a licensed physician] **AN**  
11 **AUTHORIZED PRESCRIBER** and a licensed pharmacist pursuant to a  
12 [physician–pharmacist] **PRESCRIBER–PHARMACIST** agreement and protocol under this  
13 subtitle[.]; **AND**

14 [(2)] (3) [A therapy management contract shall be related] **RELATED** to  
15 treatment using drug therapy, laboratory tests, or medical devices, under defined  
16 conditions or limitations for the purpose of improving patient outcomes.

17 12–6A–02.

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

20 12–6A–03.

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

24 (b) (1) [A licensed physician] **AN AUTHORIZED PRESCRIBER** who has  
25 entered into a [physician–pharmacist] **PRESCRIBER–PHARMACIST** agreement shall  
26 submit to the [Board of Physicians] **HEALTH OCCUPATIONS BOARD THAT REGULATES**  
27 **THE AUTHORIZED PRESCRIBER** a copy of the [physician–pharmacist]  
28 **PRESCRIBER–PHARMACIST** agreement and any subsequent modifications made to the  
29 [physician–pharmacist] **PRESCRIBER–PHARMACIST** agreement or the protocols specified  
30 in the [physician–pharmacist] **PRESCRIBER–PHARMACIST** agreement.

31 (2) A licensed pharmacist who has entered into a [physician–pharmacist]  
32 **PRESCRIBER–PHARMACIST** agreement shall submit to the Board of Pharmacy a copy of  
33 the [physician–pharmacist] **PRESCRIBER–PHARMACIST** agreement and any subsequent

1 modifications made to the [~~physician–pharmacist~~] ~~PRESCRIBER–PHARMACIST~~  
2 agreement or the protocols specified in the [~~physician–pharmacist~~]  
3 ~~PRESCRIBER–PHARMACIST~~ agreement.

4 12–6A–04.

5 A pharmacist is authorized to enter into a [~~physician–pharmacist~~]  
6 ~~PRESCRIBER–PHARMACIST~~ agreement if the pharmacist:

7 (1) Is a licensed pharmacist;

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

10 (3) Is approved by the Board to enter into a [~~physician–pharmacist~~]  
11 ~~PRESCRIBER–PHARMACIST~~ agreement with [~~a licensed physician~~] ~~AN AUTHORIZED~~  
12 ~~PRESCRIBER~~ in accordance with this subtitle; and

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

15 12–6A–05.

16 (a) Subject to the regulations adopted under this subtitle, a licensed pharmacist  
17 may enter into a therapy management contract initiated by [~~a licensed physician~~] ~~AN~~  
18 ~~AUTHORIZED PRESCRIBER~~.

19 (b) A licensed pharmacist may not employ or provide economic incentives to [~~a~~  
20 ~~licensed physician~~] ~~AN AUTHORIZED PRESCRIBER~~ for the purpose of entering into a  
21 [~~physician–pharmacist~~] ~~PRESCRIBER–PHARMACIST~~ agreement or a therapy  
22 management contract.

23 12–6A–06.

24 (a) A protocol under this subtitle:

25 (1) May authorize:

26 (i) The ~~INITIATION~~, modification, continuation, and  
27 discontinuation of drug therapy under written, disease–state specific protocols;

28 (ii) The ordering of laboratory tests; and

29 (iii) Other patient care management measures related to monitoring  
30 or improving the outcomes of drug or device therapy; and

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

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

6 12-6A-07.

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

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

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

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

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

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

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

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

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

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

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

31 12-6A-08.

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

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

6 12-6A-10.

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

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

11 (1) Shall include provisions that:

12 (i) Define the criteria for [physician-pharmacist]  
13 **PRESCRIBER-PHARMACIST** agreements; and

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

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

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