

SENATE BILL 347

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CF HB 716

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

Introduced and read first time: February 6, 2015

Assigned to: Education, Health, and Environmental Affairs

Committee Report: Favorable with amendments

Senate action: Adopted

Read second time: March 17, 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.



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.

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

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

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

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

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

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

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

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

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

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

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

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

12–6A–02.

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

12–6A–03.

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

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

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

12–6A–04.

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

(1) Is a licensed pharmacist;

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

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

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

12–6A–05.

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

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

12–6A–06.

(a) A protocol under this subtitle:

(1) May authorize:

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

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

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

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

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

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

12-6A-07.

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

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

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

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

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

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

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

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

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

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

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

12–6A–08.

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

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

12–6A–10.

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

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

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

(1) Shall include provisions that:

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

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

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

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

Approved:

Governor.

President of the Senate.

Speaker of the House of Delegates.