

Chapter 269

(House Bill 716)

AN ACT concerning

Health Occupations – Prescriber–Pharmacist Agreements and Therapy Management Contracts

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

[(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;

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

~~(ii)~~ **(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 IN CONSULTATION WITH THE BOARD OF PODIATRIC MEDICAL EXAMINERS AND THE BOARD OF NURSING**, shall jointly develop and adopt regulations to implement the provisions of this subtitle.

(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 by the Governor, May 12, 2015.