HOUSE BILL 716

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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

Committee Report: Favorable with amendments
House action: Adopted
Read second time: March 20, 2015

CHAPTER _____

1 AN ACT concerning

Health Occupations – Prescriber–Pharmacist Agreements and Therapy
Management Contracts

4 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

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.

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.

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.

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.
(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) The initiation, modification, continuation, and discontinuation of drug therapy under written, disease–state specific protocols;

(iii) The ordering of laboratory tests; and

(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 MAY AUTHORIZE the substitution of a chemically dissimilar drug product by the pharmacist for the product prescribed by the AUTHORIZED PRESCRIBER, unless permitted in the therapy management contract.

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]
1 PRESCRIBER–PHARMACIST agreement or the protocols specified in a

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

Approved:

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                                        Governor.

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                                        Speaker of the House of Delegates.

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                                        President of the Senate.