

CHAPTER 314

(Senate Bill 791)

AN ACT concerning

Group Model Health Maintenance Organizations – Drug Therapy Management

FOR the purpose of requiring certain physicians and certain pharmacists who provide certain drug therapy management to certain patients to have certain physician–pharmacist agreements approved by the State Board of Pharmacy and the State Board of Physicians; authorizing certain drug therapy management to be provided under certain circumstances; authorizing certain pharmacists to enter into certain agreements; requiring certain agreements to prohibit certain substitutions of certain drug products, subject to certain exceptions; *prohibiting the Boards from approving a physician–pharmacist agreement under certain circumstances; providing for the duration and renewal of a physician–pharmacist agreement;* authorizing certain patients to decline to participate or withdraw from certain drug therapy management at certain times; requiring certain physicians and certain pharmacists to make certain disclosures to certain patients and to obtain certain consent from certain patients following certain disclosures; defining certain terms; altering a certain definition; ~~requiring the Board of Pharmacy and the Board of Physicians to submit a certain report to the Governor and the General Assembly on or before a certain date; providing for the termination of this Act;~~ and generally relating to drug therapy management of patients in group model health maintenance organizations.

BY repealing and reenacting, without amendments,
Article – Health – General
Section 19–701(g)
Annotated Code of Maryland
(2005 Replacement Volume and 2008 Supplement)

BY adding to
Article – Health – General
Section 19–713.6
Annotated Code of Maryland
(2005 Replacement Volume and 2008 Supplement)

BY repealing and reenacting, without amendments,
Article – Health Occupations
Section 12–101(a)
Annotated Code of Maryland

(2005 Replacement Volume and 2008 Supplement)

BY repealing and reenacting, with amendments,

Article – Health Occupations

Section ~~12-6A-01~~ 12-101(s)(1), 12-6A-01, and 12-6A-02

Annotated Code of Maryland

(2005 Replacement Volume and 2008 Supplement)

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

Article – Health – General

19-701.

(g) “Health maintenance organization” means any person, including a profit or nonprofit corporation organized under the laws of any state or country, that:

(1) Operates or proposes to operate in this State;

(2) Except as provided in § 19-703(b) and (f) of this subtitle, provides or otherwise makes available to its members health care services that include at least physician, hospitalization, laboratory, X-ray, emergency, and preventive services, out-of-area coverage, and any other health care services that the Commissioner determines to be available generally on an insured or prepaid basis in the area serviced by the health maintenance organization, and, at the option of the health maintenance organization, may provide additional coverage;

(3) Except for any copayment or deductible arrangement, is compensated only on a predetermined periodic rate basis for providing to members the minimum services that are specified in item (2) of this subsection;

(4) Assures its subscribers and members, the Commissioner, and the Department that one clearly specified legal and administrative focal point or element of the health maintenance organization has the responsibility of providing the availability, accessibility, quality, and effective use of comprehensive health care services; and

(5) Primarily provides services of physicians:

(i) Directly through physicians who are either employees or partners of the health maintenance organization; or

(ii) Under arrangements with one or more groups of physicians, who are organized on a group practice or individual practice basis, under which each group:

1. Is compensated for its services primarily on the basis of an aggregate fixed sum or on a per capita basis; and

2. Is provided with an effective incentive to avoid unnecessary inpatient use, whether the individual physician members of the group are paid on a fee-for-service or other basis.

19-713.6.

(A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE MEANINGS INDICATED.

(2) “DOCUMENTED INFORMED CONSENT” MEANS:

(I) A WRITTEN CONSENT FORM SIGNED BY A PATIENT; OR

(II) VERBAL OR OTHERWISE COMMUNICATED CONSENT SIGNIFIED BY A NOTATION IN A PATIENT’S ELECTRONIC MEDICAL RECORD MAINTAINED BY A GROUP MODEL HEALTH MAINTENANCE ORGANIZATION.

(3) “DRUG THERAPY MANAGEMENT” MEANS TREATMENT OF A PATIENT USING DRUG THERAPY, LABORATORY TESTS, OR MEDICAL DEVICES UNDER CONDITIONS OR LIMITATIONS SET FORTH IN A PROTOCOL SPECIFIED IN A PHYSICIAN-PHARMACIST AGREEMENT FOR THE PURPOSE OF IMPROVING PATIENT OUTCOME.

(4) “GROUP MODEL HEALTH MAINTENANCE ORGANIZATION” MEANS A HEALTH MAINTENANCE ORGANIZATION THAT ~~PROVIDES FOR THE DELIVERY OF COVERED SERVICES TO ITS MEMBERS BY PHYSICIANS WHO ARE MEMBERS OF ONE OR MORE GROUP PRACTICES UNDER CONTRACT WITH THE HEALTH MAINTENANCE ORGANIZATION TO PROVIDE HEALTH CARE SERVICES TO THE MEMBERS OF THE HEALTH MAINTENANCE ORGANIZATION AT MEDICAL FACILITIES OWNED AND OPERATED BY THE HEALTH MAINTENANCE ORGANIZATION;~~

(I) CONTRACTS WITH ONE MULTISPECIALTY GROUP OF PHYSICIANS WHO ARE EMPLOYED BY AND SHAREHOLDERS OF THE MULTISPECIALTY GROUP; AND

(II) PROVIDES AND ARRANGES FOR THE PROVISION OF PHYSICIAN SERVICES TO PATIENTS AT MEDICAL FACILITIES OPERATED BY THE HEALTH MAINTENANCE ORGANIZATION.

(5) **“LICENSED PHARMACIST” MEANS AN INDIVIDUAL WHO IS LICENSED TO PRACTICE PHARMACY UNDER TITLE 12 OF THE HEALTH OCCUPATIONS ARTICLE.**

(6) **“LICENSED PHYSICIAN” MEANS AN INDIVIDUAL WHO IS LICENSED TO PRACTICE MEDICINE UNDER TITLE 14 OF THE HEALTH OCCUPATIONS ARTICLE.**

(7) **“PATIENT” ~~MEANS A~~ MEANS:**

(I) A PATIENT WHO IS A MEMBER OF A GROUP MODEL HEALTH MAINTENANCE ORGANIZATION; OR

(II) AN INDIVIDUAL TO WHOM THE GROUP MODEL HEALTH MAINTENANCE ORGANIZATION IS CONTRACTUALLY OR LEGALLY OBLIGATED TO PROVIDE, OR ARRANGE TO PROVIDE, HEALTH CARE SERVICES.

(8) **“PHYSICIAN-PHARMACIST AGREEMENT” MEANS AN APPROVED AGREEMENT BETWEEN A LICENSED PHYSICIAN AND A LICENSED PHARMACIST THAT IS DISEASE-STATE SPECIFIC AND SPECIFIES THE PROTOCOLS THAT MAY BE USED.**

(9) **“PROTOCOL” MEANS A COURSE OF TREATMENT PREDETERMINED BY THE LICENSED PHYSICIAN AND LICENSED PHARMACIST ACCORDING TO GENERALLY ACCEPTED MEDICAL PRACTICE FOR THE PROPER COMPLETION OF A PARTICULAR THERAPEUTIC OR DIAGNOSTIC INTERVENTION.**

(B) (1) **IN A GROUP MODEL HEALTH MAINTENANCE ORGANIZATION, A LICENSED PHYSICIAN AND A LICENSED PHARMACIST WHO WISH TO PROVIDE DRUG THERAPY MANAGEMENT TO PATIENTS SHALL HAVE A PHYSICIAN-PHARMACIST AGREEMENT THAT IS APPROVED BY THE STATE BOARD OF PHARMACY AND THE STATE BOARD OF PHYSICIANS.**

(2) **DRUG THERAPY MANAGEMENT SHALL BE PROVIDED UNDER THIS SECTION ONLY:**

(I) **IN ACCORDANCE WITH A PHYSICIAN-PHARMACIST AGREEMENT; AND**

(II) **THROUGH THE INTERNAL PHARMACY OPERATIONS OF THE GROUP MODEL HEALTH MAINTENANCE ORGANIZATION.**

(C) A LICENSED PHARMACIST IS AUTHORIZED TO ENTER INTO A PHYSICIAN-PHARMACIST AGREEMENT IF THE LICENSED PHARMACIST:

(1) HAS A DOCTOR OF PHARMACY DEGREE OR EQUIVALENT TRAINING AS ESTABLISHED IN REGULATIONS ADOPTED BY THE STATE BOARD OF PHARMACY;

(2) IS APPROVED BY THE STATE BOARD OF PHARMACY TO ENTER INTO A PHYSICIAN-PHARMACIST AGREEMENT WITH A LICENSED PHYSICIAN; AND

(3) MEETS ANY OTHER REQUIREMENTS ESTABLISHED BY REGULATION BY THE STATE BOARD OF PHARMACY.

(D) A PHYSICIAN-PHARMACIST AGREEMENT SHALL PROHIBIT THE SUBSTITUTION OF A CHEMICALLY DISSIMILAR DRUG PRODUCT BY THE PHARMACIST FOR THE PRODUCT PRESCRIBED BY THE PHYSICIAN, UNLESS PERMITTED IN THE PROTOCOL SPECIFIED IN THE PHYSICIAN-PHARMACIST AGREEMENT.

(E) THE BOARD OF PHYSICIANS AND THE BOARD OF PHARMACY MAY NOT APPROVE A PHYSICIAN-PHARMACIST AGREEMENT IF THE BOARDS FIND THAT THERE IS:

(1) INADEQUATE TRAINING, EXPERIENCE, OR EDUCATION OF THE PHYSICIANS OR PHARMACISTS TO IMPLEMENT THE PROTOCOL OR PROTOCOLS SPECIFIED IN THE PHYSICIAN-PHARMACIST AGREEMENT; OR

(2) A FAILURE TO SATISFY THE REQUIREMENTS OF:

(I) THIS SECTION OR TITLE 14 OF THE HEALTH OCCUPATIONS ARTICLE; OR

(II) ANY REGULATIONS ADOPTED BY THE BOARD OF PHYSICIANS AND THE BOARD OF PHARMACY UNDER THIS SECTION.

(F) A PHYSICIAN-PHARMACIST AGREEMENT UNDER THIS SECTION SHALL BE VALID FOR 2 YEARS FROM THE DATE OF ITS FINAL APPROVAL BY THE BOARD OF PHYSICIANS AND THE BOARD OF PHARMACY AND MAY BE RENEWED FOR ADDITIONAL 2-YEAR TERMS WITH APPROVAL FROM THE BOARD OF PHYSICIANS AND THE BOARD OF PHARMACY.

~~(E)~~ (G) A PATIENT MAY DECLINE TO PARTICIPATE OR WITHDRAW FROM PARTICIPATING IN DRUG THERAPY MANAGEMENT IN A GROUP MODEL HEALTH MAINTENANCE ORGANIZATION AT ANY TIME.

~~(F)~~ (H) A LICENSED PHYSICIAN OR LICENSED PHARMACIST OR BOTH SHALL INFORM A PATIENT:

(1) REGARDING THE PROCEDURES THAT WILL BE UTILIZED FOR DRUG THERAPY MANAGEMENT UNDER THE ASSOCIATED PROTOCOLS;

(2) THAT THE PATIENT MAY DECLINE TO PARTICIPATE OR WITHDRAW FROM PARTICIPATING IN THE DRUG THERAPY MANAGEMENT AT ANY TIME; AND

(3) THAT NEITHER THE PHYSICIAN NOR THE PHARMACIST HAS BEEN COERCED, GIVEN ECONOMIC INCENTIVES, EXCLUDING NORMAL REIMBURSEMENT FOR SERVICES RENDERED, OR INVOLUNTARILY REQUIRED TO PARTICIPATE.

~~(G)~~ (I) A LICENSED PHYSICIAN OR A LICENSED PHARMACIST OR BOTH SHALL OBTAIN DOCUMENTED INFORMED CONSENT FROM A PATIENT AFTER DISCLOSING THE INFORMATION REQUIRED TO BE DISCLOSED UNDER SUBSECTION ~~(F)~~ (H) OF THIS SECTION.

Article - Health Occupations

12-101.

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

(s) (1) “Practice pharmacy” means to engage in any of the following activities:

(i) Providing pharmaceutical care;

(ii) Compounding, dispensing, or distributing prescription drugs or devices;

(iii) Compounding or dispensing nonprescription drugs or devices;

(iv) Monitoring prescriptions for prescription and nonprescription drugs or devices;

(v) Providing information, explanation, or recommendations to patients and health care practitioners about the safe and effective use of prescription or nonprescription drugs or devices;

(vi) Identifying and appraising problems concerning the use or monitoring of therapy with drugs or devices;

(vii) Acting within the parameters of a therapy management contract, as provided under Subtitle 6A of this title;

(viii) Administering an influenza vaccination in accordance with § 12-508 of this title;

(ix) Delegating a pharmacy act to a registered pharmacy technician, pharmacy student, or an individual engaged in a Board approved pharmacy technician training program; [or]

(x) Supervising a delegated pharmacy act performed by a registered pharmacy technician, pharmacy student, or an individual engaged in a Board approved pharmacy technician training program; OR

(XI) PROVIDING DRUG THERAPY MANAGEMENT IN ACCORDANCE WITH § 19-713.6 OF THE HEALTH - GENERAL ARTICLE.

12-6A-01.

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

(B) “GROUP MODEL HEALTH MAINTENANCE ORGANIZATION” MEANS A HEALTH MAINTENANCE ORGANIZATION THAT PROVIDES FOR THE DELIVERY OF COVERED SERVICES TO ITS MEMBERS BY PHYSICIANS WHO ARE MEMBERS OF ONE OR MORE GROUP PRACTICES UNDER CONTRACT WITH THE HEALTH MAINTENANCE ORGANIZATION TO PROVIDE HEALTH CARE SERVICES TO THE MEMBERS OF THE HEALTH MAINTENANCE ORGANIZATION AT MEDICAL FACILITIES OWNED AND OPERATED BY THE HEALTH MAINTENANCE ORGANIZATION HAS THE MEANING STATED IN § 19-713.6 OF THE HEALTH - GENERAL ARTICLE.

(C) “HEALTH MAINTENANCE ORGANIZATION” HAS THE MEANING STATED IN § 19-701(G) OF THE HEALTH - GENERAL ARTICLE.

[(b)] (D) (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.

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

[(d)] (F) “Physician–pharmacist agreement” means an approved agreement between a licensed physician and a licensed pharmacist that is disease–state specific and specifies the protocols that may be used.

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

[(f)] (H) (1) “Therapy management contract” means a voluntary, written arrangement that is disease–state specific 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 and alternate designated licensed physicians involved directly in patient care; and

(iii) One patient receiving care from a licensed physician and a licensed pharmacist pursuant to a physician–pharmacist agreement and protocol under this subtitle.

(2) A therapy management contract shall be 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.**

~~SECTION 2. AND BE IT FURTHER ENACTED, That:~~

~~On or before December 1, 2012, the Board of Pharmacy and the Board of Physicians shall report to the Governor and, in accordance with § 2–1246 of the State Government Article, the General Assembly on:~~

~~(1) the effect of this Act and any recommendations for legislative or regulatory action; and~~

~~(2) the outcomes achieved by drug therapy management as provided for under this Act.~~

SECTION ~~2. 3.~~ 2. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2009. ~~It shall remain in effect for a period of 4 years and, at the end of September 30, 2013, with no further action required by the General Assembly, this Act shall be abrogated and of no further force and effect.~~

Approved by the Governor, May 7, 2009.