

SENATE BILL 791

J2, J3, J4

(9lr2470)

ENROLLED BILL

—Finance and Education, Health, and Environmental Affairs/Health and Government Operations—

Introduced by **Senator Klausmeier**

Read and Examined by Proofreaders:

Proofreader.

Proofreader.

Sealed with the Great Seal and presented to the Governor, for his approval this

_____ day of _____ at _____ o'clock, _____ M.

President.

CHAPTER _____

1 AN ACT concerning

2 **Group Model Health Maintenance Organizations - Drug Therapy**
3 **Management**

4 FOR the purpose of requiring certain physicians and certain pharmacists who provide
5 certain drug therapy management to certain patients to have certain
6 physician-pharmacist agreements approved by the State Board of Pharmacy
7 and the State Board of Physicians; authorizing certain drug therapy
8 management to be provided under certain circumstances; authorizing certain
9 pharmacists to enter into certain agreements; requiring certain agreements to
10 prohibit certain substitutions of certain drug products, subject to certain
11 exceptions; *prohibiting the Boards from approving a physician-pharmacist*
12 *agreement under certain circumstances; providing for the duration and renewal*
13 *of a physician-pharmacist agreement;* authorizing certain patients to decline to
14 participate or withdraw from certain drug therapy management at 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.

Italics indicate opposite chamber / conference committee amendments.



1 times; requiring certain physicians and certain pharmacists to make certain
 2 disclosures to certain patients and to obtain certain consent from certain
 3 patients following certain disclosures; altering a certain
 4 definition; ~~requiring the Board of Pharmacy and the Board of Physicians to~~
 5 ~~submit a certain report to the Governor and the General Assembly on or before~~
 6 ~~a certain date; providing for the termination of this Act;~~ and generally relating
 7 to drug therapy management of patients in group model health maintenance
 8 organizations.

9 BY repealing and reenacting, without amendments,
 10 Article – Health – General
 11 Section 19–701(g)
 12 Annotated Code of Maryland
 13 (2005 Replacement Volume and 2008 Supplement)

14 BY adding to
 15 Article – Health – General
 16 Section 19–713.6
 17 Annotated Code of Maryland
 18 (2005 Replacement Volume and 2008 Supplement)

19 BY repealing and reenacting, without amendments,
 20 Article – Health Occupations
 21 Section 12–101(a)
 22 Annotated Code of Maryland
 23 (2005 Replacement Volume and 2008 Supplement)

24 BY repealing and reenacting, with amendments,
 25 Article – Health Occupations
 26 Section ~~12–6A–01~~ 12–101(s)(1), 12–6A–01, and 12–6A–02
 27 Annotated Code of Maryland
 28 (2005 Replacement Volume and 2008 Supplement)

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

31 **Article – Health – General**

32 19–701.

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

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

36 (2) Except as provided in § 19–703(b) and (f) of this subtitle, provides
 37 or otherwise makes available to its members health care services that include at least

1 physician, hospitalization, laboratory, X-ray, emergency, and preventive services,
2 out-of-area coverage, and any other health care services that the Commissioner
3 determines to be available generally on an insured or prepaid basis in the area
4 serviced by the health maintenance organization, and, at the option of the health
5 maintenance organization, may provide additional coverage;

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

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

14 (5) Primarily provides services of physicians:

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

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

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

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

25 **19-713.6.**

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

28 (2) **“DOCUMENTED INFORMED CONSENT” MEANS:**

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

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

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

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

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

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

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

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

26 (7) “PATIENT” ~~MEANS A~~ MEANS:

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

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

32 (8) “PHYSICIAN–PHARMACIST AGREEMENT” MEANS AN
33 APPROVED AGREEMENT BETWEEN A LICENSED PHYSICIAN AND A LICENSED
34 PHARMACIST THAT IS DISEASE–STATE SPECIFIC AND SPECIFIES THE
35 PROTOCOLS THAT MAY BE USED.

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

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

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

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

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

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

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

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

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

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

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

1 12-101.

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

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

5 (i) Providing pharmaceutical care;

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

8 (iii) Compounding or dispensing nonprescription drugs or
9 devices;

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

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

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

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

19 (viii) Administering an influenza vaccination in accordance with §
20 12-508 of this title;

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

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

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

29 12-6A-01.

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

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

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

12 **[(b)] (D)** (1) “**Institutional facility**” means a facility other than a nursing
13 home whose primary purpose is to provide a physical environment for patients to
14 obtain inpatient or emergency care.

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

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

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

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

26 **[(f)] (H)** (1) “**Therapy management contract**” means a voluntary, written
27 arrangement that is disease-state specific signed by each party to the arrangement
28 between:

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

31 (ii) One licensed physician and alternate designated licensed
32 physicians involved directly in patient care; and

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

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

7 12–6A–02.

8 A therapy management contract is not required for the management of patients
9 in an institutional facility **OR IN A GROUP MODEL HEALTH MAINTENANCE**
10 **ORGANIZATION.**

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

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

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

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

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

Approved:

Governor.

President of the Senate.

Speaker of the House of Delegates.