

SENATE BILL 791

J2, J3, J4

9lr2470
CF HB 725

By: **Senator Klausmeier**

Introduced and read first time: February 6, 2009

Assigned to: Finance and Education, Health, and Environmental Affairs

Committee Report: Favorable with amendments

Senate action: Adopted

Read second time: March 10, 2009

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; authorizing certain patients to decline to participate or withdraw
12 from certain drug therapy management at certain times; requiring certain
13 physicians and certain pharmacists to make certain disclosures to certain
14 patients and to obtain certain consent from certain patients following certain
15 disclosures; defining certain terms; altering a certain definition; requiring the
16 Board of Pharmacy and the Board of Physicians to submit a certain report to
17 the Governor and the General Assembly on or before a certain date; providing
18 for the termination of this Act; and generally relating to drug therapy
19 management of patients in group model health maintenance organizations.

20 BY repealing and reenacting, without amendments,
21 Article – Health – General
22 Section 19–701(g)
23 Annotated Code of Maryland
24 (2005 Replacement Volume and 2008 Supplement)

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.



1 BY adding to
2 Article – Health – General
3 Section 19–713.6
4 Annotated Code of Maryland
5 (2005 Replacement Volume and 2008 Supplement)

6 BY repealing and reenacting, without amendments,
7 Article – Health Occupations
8 Section 12–101(a)
9 Annotated Code of Maryland
10 (2005 Replacement Volume and 2008 Supplement)

11 BY repealing and reenacting, with amendments,
12 Article – Health Occupations
13 Section ~~12–6A–01~~ 12–101(s)(1), 12–6A–01, and 12–6A–02
14 Annotated Code of Maryland
15 (2005 Replacement Volume and 2008 Supplement)

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

18 **Article – Health – General**

19 19–701.

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

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

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

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

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

- 1 (5) Primarily provides services of physicians:
- 2 (i) Directly through physicians who are either employees or
3 partners of the health maintenance organization; or
- 4 (ii) Under arrangements with one or more groups of physicians,
5 who are organized on a group practice or individual practice basis, under which each
6 group:
- 7 1. Is compensated for its services primarily on the basis
8 of an aggregate fixed sum or on a per capita basis; and
- 9 2. Is provided with an effective incentive to avoid
10 unnecessary inpatient use, whether the individual physician members of the group are
11 paid on a fee-for-service or other basis.

12 **19-713.6.**

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

15 (2) "DOCUMENTED INFORMED CONSENT" MEANS:

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

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

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

25 (4) "GROUP MODEL HEALTH MAINTENANCE ORGANIZATION"
26 MEANS A HEALTH MAINTENANCE ORGANIZATION THAT ~~PROVIDES FOR THE~~
27 ~~DELIVERY OF COVERED SERVICES TO ITS MEMBERS BY PHYSICIANS WHO ARE~~
28 ~~MEMBERS OF ONE OR MORE GROUP PRACTICES UNDER CONTRACT WITH THE~~
29 ~~HEALTH MAINTENANCE ORGANIZATION TO PROVIDE HEALTH CARE SERVICES~~
30 ~~TO THE MEMBERS OF THE HEALTH MAINTENANCE ORGANIZATION AT MEDICAL~~
31 ~~FACILITIES OWNED AND OPERATED BY THE HEALTH MAINTENANCE~~
32 ~~ORGANIZATION;~~

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

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

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

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

13 **(7) “PATIENT” ~~MEANS A~~ MEANS:**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

23 (F) A LICENSED PHYSICIAN OR LICENSED PHARMACIST OR BOTH SHALL
24 INFORM A PATIENT:

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

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

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

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

5 Article - Health Occupations

6 12-101.

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

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

10 (i) Providing pharmaceutical care;

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

13 (iii) Compounding or dispensing nonprescription drugs or
14 devices;

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

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

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

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

24 (viii) Administering an influenza vaccination in accordance with §
25 12-508 of this title;

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

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

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

3 12-6A-01.

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

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

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

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

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

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

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

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

30 [(f)] (H) (1) “Therapy management contract” means a voluntary, written
 31 arrangement that is disease–state specific signed by each party to the arrangement
 32 between:

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

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

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

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

9 12–6A–02.

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

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

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

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

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

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

Approved:

Governor.

President of the Senate.

Speaker of the House of Delegates.