

SENATE BILL 791

J2, J3, J4

9lr2470
CF 9lr3032

By: **Senator Klausmeier**

Introduced and read first time: February 6, 2009

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

A BILL ENTITLED

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; and generally relating to drug therapy
16 management of patients in group model health maintenance organizations.

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

22 BY adding to
23 Article – Health – General
24 Section 19–713.6
25 Annotated Code of Maryland
26 (2005 Replacement Volume and 2008 Supplement)

27 BY repealing and reenacting, with amendments,
28 Article – Health Occupations

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 Section 12-6A-01 and 12-6A-02
2 Annotated Code of Maryland
3 (2005 Replacement Volume and 2008 Supplement)

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

6 **Article - Health - General**

7 19-701.

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

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

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

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

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

26 (5) Primarily provides services of physicians:

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

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

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

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

4 **19-713.6.**

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

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

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

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

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

17 (4) **“GROUP MODEL HEALTH MAINTENANCE ORGANIZATION”**
18 **MEANS A HEALTH MAINTENANCE ORGANIZATION THAT PROVIDES FOR THE**
19 **DELIVERY OF COVERED SERVICES TO ITS MEMBERS BY PHYSICIANS WHO ARE**
20 **MEMBERS OF ONE OR MORE GROUP PRACTICES UNDER CONTRACT WITH THE**
21 **HEALTH MAINTENANCE ORGANIZATION TO PROVIDE HEALTH CARE SERVICES**
22 **TO THE MEMBERS OF THE HEALTH MAINTENANCE ORGANIZATION AT MEDICAL**
23 **FACILITIES OWNED AND OPERATED BY THE HEALTH MAINTENANCE**
24 **ORGANIZATION.**

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

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

31 (7) **“PATIENT” MEANS A PATIENT WHO IS A MEMBER OF A GROUP**
32 **MODEL HEALTH MAINTENANCE ORGANIZATION.**

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

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

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

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

16 **(I) IN ACCORDANCE WITH A PHYSICIAN–PHARMACIST**
17 **AGREEMENT; AND**

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

20 **(C) A LICENSED PHARMACIST IS AUTHORIZED TO ENTER INTO A**
21 **PHYSICIAN–PHARMACIST AGREEMENT IF THE LICENSED PHARMACIST:**

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

25 **(2) IS APPROVED BY THE STATE BOARD OF PHARMACY TO ENTER**
26 **INTO A PHYSICIAN–PHARMACIST AGREEMENT WITH A LICENSED PHYSICIAN;**
27 **AND**

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

30 **(D) A PHYSICIAN–PHARMACIST AGREEMENT SHALL PROHIBIT THE**
31 **SUBSTITUTION OF A CHEMICALLY DISSIMILAR DRUG PRODUCT BY THE**
32 **PHARMACIST FOR THE PRODUCT PRESCRIBED BY THE PHYSICIAN, UNLESS**
33 **PERMITTED IN THE PROTOCOL SPECIFIED IN THE PHYSICIAN–PHARMACIST**
34 **AGREEMENT.**

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

4 **(F) A LICENSED PHYSICIAN OR LICENSED PHARMACIST OR BOTH SHALL**
5 **INFORM A PATIENT:**

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

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

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

15 **(G) A LICENSED PHYSICIAN OR A LICENSED PHARMACIST OR BOTH**
16 **SHALL OBTAIN DOCUMENTED INFORMED CONSENT FROM A PATIENT AFTER**
17 **DISCLOSING THE INFORMATION REQUIRED TO BE DISCLOSED UNDER**
18 **SUBSECTION (F) OF THIS SECTION.**

19 **Article – Health Occupations**

20 12–6A–01.

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

22 **(B) “GROUP MODEL HEALTH MAINTENANCE ORGANIZATION” MEANS A**
23 **HEALTH MAINTENANCE ORGANIZATION THAT PROVIDES FOR THE DELIVERY OF**
24 **COVERED SERVICES TO ITS MEMBERS BY PHYSICIANS WHO ARE MEMBERS OF**
25 **ONE OR MORE GROUP PRACTICES UNDER CONTRACT WITH THE HEALTH**
26 **MAINTENANCE ORGANIZATION TO PROVIDE HEALTH CARE SERVICES TO THE**
27 **MEMBERS OF THE HEALTH MAINTENANCE ORGANIZATION AT MEDICAL**
28 **FACILITIES OWNED AND OPERATED BY THE HEALTH MAINTENANCE**
29 **ORGANIZATION.**

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

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

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

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

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

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

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

18 (i) One licensed pharmacist and the licensed pharmacist’s
19 designated alternate licensed pharmacists;

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

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

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

28 12–6A–02.

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

32 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
33 October 1, 2009.