

# HOUSE BILL 725

J2, J3, J4

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CF SB 791

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By: **Delegates Tarrant, Benson, Bromwell, Costa, Pena-Melnyk, Reznik, Riley, and V. Turner**

Introduced and read first time: February 10, 2009

Assigned to: Health and Government Operations

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Committee Report: Favorable with amendments

House action: Adopted

Read second time: March 24, 2009

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## 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  
15 times; requiring certain physicians and certain pharmacists to make certain  
16 disclosures to certain patients and to obtain certain consent from certain  
17 patients following certain disclosures; defining certain terms; altering a certain  
18 definition; and generally relating to drug therapy management of patients in  
19 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)

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

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

26 (2) A FAILURE TO SATISFY THE REQUIREMENTS OF:

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

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

31 (F) A PHYSICIAN-PHARMACIST AGREEMENT UNDER THIS SECTION  
32 SHALL BE VALID FOR 2 YEARS FROM THE DATE OF ITS FINAL APPROVAL BY THE  
33 BOARD OF PHYSICIANS AND THE BOARD OF PHARMACY AND MAY BE RENEWED

1 FOR ADDITIONAL 2-YEAR TERMS WITH APPROVAL FROM THE BOARD OF  
 2 PHYSICIANS AND THE BOARD OF PHARMACY.

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

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

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

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

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

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

21 **Article - Health Occupations**

22 12-101.

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

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

26 (i) Providing pharmaceutical care;

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

29 (iii) Compounding or dispensing nonprescription drugs or  
 30 devices;

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

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

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

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

8                   (viii) Administering an influenza vaccination in accordance with §  
9 12-508 of this title;

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

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

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

18 12-6A-01.

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

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

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

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

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

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

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

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

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

15                           (i)    One licensed pharmacist and the licensed pharmacist’s  
16 designated alternate licensed pharmacists;

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

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

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

25   12–6A–02.

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

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