J2, J3, J4

9lr3032 CF SB 791

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Introduced and read first time: February 10, 2009 Assigned to: Health and Government Operations

A BILL ENTITLED

1 AN ACT concerning

2 3

Group Model Health Maintenance Organizations – Drug Therapy 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 physician-pharmacist agreements approved by the State Board of Pharmacy 6 and the State Board of Physicians; authorizing certain drug therapy 7 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 exceptions; authorizing certain patients to decline to participate or withdraw 11 from certain drug therapy management at certain times; requiring certain 12 13 physicians and certain pharmacists to make certain disclosures to certain patients and to obtain certain consent from certain patients following certain 14 disclosures; defining certain terms; and generally relating to drug therapy 15management of patients in group model health maintenance organizations. 16
- 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,



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HOUSE BILL 725

$1 \\ 2 \\ 3 \\ 4$	Article – Health Occupations Section 12–6A–01 and 12–6A–02 Annotated Code of Maryland (2005 Replacement Volume and 2008 Supplement)
$5 \\ 6$	SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:
7	Article – Health – General
8	19–701.
9 10	(g) "Health maintenance organization" means any person, including a profit or nonprofit corporation organized under the laws of any state or country, that:
11	(1) Operates or proposes to operate in this State;
12 13 14 15 16 17 18	(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;
19 20 21	(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;
22 23 24 25 26	(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
27	(5) Primarily provides services of physicians:
28 29	$(i) \qquad \mbox{Directly through physicians who are either employees or} \\ partners of the health maintenance organization; or \\$
$30 \\ 31 \\ 32$	(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:
33 34	1. Is compensated for its services primarily on the basis of an aggregate fixed sum or on a per capita basis; and

1 Is provided with an effective incentive to avoid 2. $\mathbf{2}$ 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 (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE (A) 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"DRUG THERAPY MANAGEMENT" MEANS TREATMENT OF A (3) 13PATIENT USING DRUG THERAPY, LABORATORY TESTS, OR MEDICAL DEVICES 14UNDER CONDITIONS OR LIMITATIONS SET FORTH IN A PROTOCOL SPECIFIED IN 15A 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 21HEALTH MAINTENANCE ORGANIZATION TO PROVIDE HEALTH CARE SERVICES 22TO THE MEMBERS OF THE HEALTH MAINTENANCE ORGANIZATION AT MEDICAL

FACILITIES OWNED AND 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 PATIENT WHO IS A MEMBER OF A GROUP
 MODEL HEALTH MAINTENANCE ORGANIZATION.

1(8) "PHYSICIAN-PHARMACIST AGREEMENT" MEANS AN2APPROVED AGREEMENT BETWEEN A LICENSED PHYSICIAN AND A LICENSED3PHARMACIST THAT IS DISEASE-STATE SPECIFIC AND SPECIFIES THE4PROTOCOLS 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 IN A GROUP MODEL HEALTH MAINTENANCE ORGANIZATION, A **(B)** (1) 10 LICENSED PHYSICIAN AND A LICENSED PHARMACIST WHO WISH TO PROVIDE 11 DRUG THERAPY MANAGEMENT ТО PATIENTS SHALL HAVE Α 12PHYSICIAN-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 A21PHYSICIAN-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

28(3) MEETS ANY OTHER REQUIREMENTS ESTABLISHED BY29REGULATION 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 HAS12BEEN COERCED, GIVEN ECONOMIC INCENTIVES, EXCLUDING NORMAL13REIMBURSEMENT FOR SERVICES RENDERED, OR INVOLUNTARILY REQUIRED TO14PARTICIPATE.

(G) 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) OF THIS SECTION.

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Article – Health Occupations

20 12–6A–01.

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

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

30(c) "Health maintenance organization" has the meaning31stated 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.

[(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;

20 (ii) One licensed physician and alternate designated licensed
 21 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.

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.

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

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

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