

HOUSE BILL 781

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2002 Regular Session
(2r1711)

ENROLLED BILL

-- *Environmental Matters/Education, Health, and Environmental Affairs* --

Introduced by **Delegates Hammen, Bozman, Elliott, Klausmeier, and**
Sophocleus Sophocleus, Sher, Morhaim, Hurson, Weir, Baldwin, Boutin,
Cane, Frush, Mohorovic, Nathan-Pulliam, Oaks, Owings, Redmer,
Stern, and Stull

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.

Speaker.

CHAPTER 249

1 AN ACT concerning

2 **Physicians and Pharmacists - Therapy Management Contracts**

3 FOR the purpose of requiring a licensed physician and a licensed pharmacist to have
4 a certain agreement before they enter into a therapy management contract;
5 requiring the agreement to meet certain requirements; requiring the Board of
6 Physician Quality Assurance and the Board of Pharmacy to approve the
7 agreements under certain circumstances; providing for the authorization of
8 certain protocols; requiring therapy management contracts to apply to certain
9 protocols; requiring a therapy management contract to terminate at a certain
10 time; requiring a therapy management contract to include certain provisions;
11 requiring a physician to maintain certain patient records; requiring the Board of
12 Physician Quality Assurance and the Board of Pharmacy to adopt regulations
13 including certain provisions; altering a certain definition; adding certain
14 definitions; providing for the termination of this Act; and generally relating to

1 therapy management contracts.

2 BY repealing and reenacting, without amendments,
3 Article - Health Occupations
4 Section 12-101(a), (i), and (m)
5 Annotated Code of Maryland
6 (2000 Replacement Volume and 2001 Supplement)

7 BY repealing and reenacting, with amendments,
8 Article - Health Occupations
9 Section 12-101(p)
10 Annotated Code of Maryland
11 (2000 Replacement Volume and 2001 Supplement)

12 BY adding to
13 Article - Health Occupations
14 Section 12-6A-01 through 12-6A-10, inclusive, to be under the new subtitle
15 "Subtitle 6A. Therapy Management Contracts"
16 Annotated Code of Maryland
17 (2000 Replacement Volume and 2001 Supplement)

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

20 **Article - Health Occupations**

21 12-101.

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

23 (i) "Licensed pharmacist" means, unless the context requires otherwise, a
24 pharmacist who is licensed by the Board to practice pharmacy.

25 (m) "Pharmacist" means an individual who practices pharmacy regardless of
26 the location where the activities of practice are performed.

27 (p) (1) "Practice pharmacy" means to engage in any of the following
28 activities:

29 (i) Providing pharmaceutical care;

30 (ii) Compounding, dispensing, or distributing prescription drugs or
31 devices;

32 (iii) Compounding or dispensing nonprescription drugs or devices;

33 (iv) Monitoring prescriptions for prescription and nonprescription
34 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; [or]

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

6 (VII) ACTING WITHIN THE PARAMETERS OF A THERAPY
7 MANAGEMENT CONTRACT, AS PROVIDED UNDER SUBTITLE 6A OF THIS TITLE.

8 (2) "Practice pharmacy" does not include the operations of a person who
9 holds a permit issued under §§ 12-601 and 12-602 of this title.

10 SUBTITLE 6A. THERAPY MANAGEMENT CONTRACTS.

11 12-6A-01.

12 (A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS
13 INDICATED.

14 (B) (1) "INSTITUTIONAL FACILITY" MEANS A FACILITY OTHER THAN A
15 NURSING HOME WHOSE PRIMARY PURPOSE IS TO PROVIDE A PHYSICAL
16 ENVIRONMENT FOR PATIENTS TO OBTAIN INPATIENT OR EMERGENCY CARE.

17 (2) "INSTITUTIONAL FACILITY" DOES NOT INCLUDE AN URGENT CARE
18 FACILITY THAT IS NOT PART OF A FACILITY.

19 (C) "LICENSED PHYSICIAN" MEANS AN INDIVIDUAL WHO IS LICENSED TO
20 PRACTICE MEDICINE UNDER TITLE 14 OF THIS ARTICLE.

21 (D) "PHYSICIAN-PHARMACIST AGREEMENT" MEANS AN APPROVED
22 AGREEMENT BETWEEN A LICENSED PHYSICIAN AND A LICENSED PHARMACIST THAT
23 IS DISEASE-STATE SPECIFIC AND SPECIFIES THE PROTOCOLS THAT MAY BE USED.

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

28 (F) (1) "THERAPY MANAGEMENT CONTRACT" MEANS A VOLUNTARY,
29 WRITTEN ARRANGEMENT THAT IS DISEASE-STATE SPECIFIC SIGNED BY EACH PARTY
30 TO THE ARRANGEMENT BETWEEN:

31 (I) ONE LICENSED PHARMACIST AND THE LICENSED
32 PHARMACIST'S DESIGNATED ALTERNATE LICENSED PHARMACISTS;

33 (II) ONE LICENSED PHYSICIAN AND ALTERNATE DESIGNATED
34 LICENSED PHYSICIANS INVOLVED DIRECTLY IN PATIENT CARE; AND

1 (III) ONE PATIENT RECEIVING CARE FROM A LICENSED PHYSICIAN
2 AND A LICENSED PHARMACIST PURSUANT TO A PHYSICIAN-PHARMACIST
3 AGREEMENT AND PROTOCOL UNDER THIS SUBTITLE.

4 (2) A THERAPY MANAGEMENT CONTRACT SHALL BE RELATED TO
5 TREATMENT USING DRUG THERAPY, LABORATORY TESTS, OR MEDICAL DEVICES,
6 UNDER DEFINED CONDITIONS OR LIMITATIONS FOR THE PURPOSE OF IMPROVING
7 PATIENT OUTCOMES.

8 12-6A-02.

9 A THERAPY MANAGEMENT CONTRACT IS NOT REQUIRED FOR THE
10 MANAGEMENT OF PATIENTS IN AN INSTITUTIONAL FACILITY.

11 12-6A-03.

12 (A) A LICENSED PHYSICIAN AND A LICENSED PHARMACIST WHO WISH TO
13 ENTER INTO THERAPY MANAGEMENT CONTRACTS SHALL HAVE A
14 PHYSICIAN-PHARMACIST AGREEMENT THAT IS APPROVED BY THE BOARD OF
15 PHARMACY AND THE BOARD OF PHYSICIAN QUALITY ASSURANCE.

16 (B) THE BOARD OF PHYSICIAN QUALITY ASSURANCE AND THE BOARD OF
17 PHARMACY MAY NOT APPROVE A PHYSICIAN-PHARMACIST AGREEMENT IF THE
18 BOARDS FIND THERE IS:

19 (1) INADEQUATE TRAINING, EXPERIENCE, OR EDUCATION OF THE
20 PHYSICIANS OR PHARMACISTS TO IMPLEMENT THE PROTOCOL OR PROTOCOLS
21 SPECIFIED IN THE AGREEMENT; OR

22 (2) A FAILURE TO SATISFY REQUIREMENTS OF:

23 (I) THIS TITLE OR TITLE 14 OF THIS ARTICLE; OR

24 (II) REGULATIONS ESTABLISHED BY THE BOARD OF PHYSICIAN
25 QUALITY ASSURANCE AND THE BOARD OF PHARMACY ADOPTED UNDER THIS
26 SUBTITLE.

27 (C) A PHYSICIAN-PHARMACIST AGREEMENT SHALL BE VALID FOR 2 YEARS
28 FROM THE DATE OF ITS FINAL APPROVAL BY THE BOARD OF PHYSICIAN QUALITY
29 ASSURANCE AND THE BOARD OF PHARMACY UNLESS RENEWED IN ACCORDANCE
30 WITH ESTABLISHED REGULATIONS ADOPTED UNDER THIS SUBTITLE.

31 12-6A-04.

32 A PHARMACIST IS AUTHORIZED TO ENTER INTO A PHYSICIAN-PHARMACIST
33 AGREEMENT IF THE PHARMACIST:

34 (1) IS A LICENSED PHARMACIST;

35 (2) HAS A DOCTOR OF PHARMACY DEGREE OR EQUIVALENT TRAINING
36 AS ESTABLISHED IN REGULATIONS ADOPTED UNDER THIS SUBTITLE;

1 (3) IS APPROVED BY THE BOARD TO ENTER INTO A
2 PHYSICIAN-PHARMACIST AGREEMENT WITH A LICENSED PHYSICIAN IN
3 ACCORDANCE WITH THIS SUBTITLE; AND

4 (4) MEETS THE REQUIREMENTS THAT ARE ESTABLISHED BY
5 REGULATIONS ADOPTED UNDER THIS SUBTITLE.

6 12-6A-05.

7 (A) SUBJECT TO THE REGULATIONS ADOPTED UNDER THIS SUBTITLE, A
8 LICENSED PHARMACIST MAY ENTER INTO A THERAPY MANAGEMENT CONTRACT
9 INITIATED BY A LICENSED PHYSICIAN.

10 (B) A LICENSED PHARMACIST MAY NOT EMPLOY OR PROVIDE ECONOMIC
11 INCENTIVES TO A LICENSED PHYSICIAN FOR THE PURPOSE OF ENTERING INTO A
12 PHYSICIAN-PHARMACIST AGREEMENT OR A THERAPY MANAGEMENT CONTRACT.

13 12-6A-06.

14 (A) A PROTOCOL UNDER THIS SUBTITLE:

15 (1) MAY AUTHORIZE:

16 (I) THE MODIFICATION, CONTINUATION, AND DISCONTINUATION
17 OF DRUG THERAPY UNDER WRITTEN, DISEASE-STATE SPECIFIC PROTOCOLS;

18 (II) THE ORDERING OF LABORATORY TESTS; AND

19 (III) OTHER PATIENT CARE MANAGEMENT MEASURES RELATED TO
20 MONITORING OR IMPROVING THE OUTCOMES OF DRUG OR DEVICE THERAPY; AND

21 (2) MAY NOT AUTHORIZE ACTS THAT EXCEED THE SCOPE OF PRACTICE
22 OF THE PARTIES TO THE THERAPY MANAGEMENT CONTRACT.

23 (B) A PROTOCOL SHALL PROHIBIT THE SUBSTITUTION OF A CHEMICALLY
24 DISSIMILAR DRUG PRODUCT BY THE PHARMACIST FOR THE PRODUCT PRESCRIBED
25 BY THE PHYSICIAN, UNLESS PERMITTED IN THE THERAPY MANAGEMENT CONTRACT.

26 12-6A-07.

27 (A) A THERAPY MANAGEMENT CONTRACT SHALL APPLY ONLY TO
28 CONDITIONS FOR WHICH PROTOCOLS HAVE BEEN APPROVED BY THE BOARD OF
29 PHYSICIAN QUALITY ASSURANCE AND THE BOARD OF PHARMACY UNDER THE
30 REGULATIONS ADOPTED UNDER THIS SUBTITLE.

31 (B) A THERAPY MANAGEMENT CONTRACT SHALL TERMINATE ONE YEAR
32 FROM THE DATE OF ITS SIGNING, UNLESS RENEWED BY THE LICENSED PHYSICIAN,
33 LICENSED PHARMACIST, AND PATIENT.

34 (C) A THERAPY MANAGEMENT CONTRACT SHALL INCLUDE:

1 (1) A STATEMENT THAT NONE OF THE PARTIES INVOLVED IN THE
2 THERAPY MANAGEMENT CONTRACT HAVE BEEN COERCED, GIVEN ECONOMIC
3 INCENTIVES, EXCLUDING NORMAL REIMBURSEMENT FOR SERVICES RENDERED, OR
4 INVOLUNTARILY REQUIRED TO PARTICIPATE;

5 (2) NOTICE TO THE PATIENT INDICATING HOW THE PATIENT MAY
6 TERMINATE THE THERAPY MANAGEMENT CONTRACT;

7 (3) A PROCEDURE FOR PERIODIC REVIEW BY THE PHYSICIAN, OF THE
8 DRUGS MODIFIED PURSUANT TO THE AGREEMENT OR CHANGED WITH THE
9 CONSENT OF THE PHYSICIAN; AND

10 (4) REFERENCE TO AN APPROVED PROTOCOL, WHICH WILL BE
11 PROVIDED TO THE PATIENT UPON REQUEST.

12 (D) ANY PARTY TO THE THERAPY MANAGEMENT CONTRACT MAY TERMINATE
13 THE CONTRACT AT ANY TIME.

14 (E) FEES PAID TO THE BOARD OF PHYSICIAN QUALITY ASSURANCE AND
15 BOARD OF PHARMACY RELATED TO THERAPY MANAGEMENT SHALL BE
16 ESTABLISHED IN REGULATIONS.

17 12-6A-08.

18 (A) THE PHYSICIAN SHALL MAINTAIN COMPLETE PATIENT RECORDS WITH
19 RESPECT TO THE THERAPY MANAGEMENT CONTRACT.

20 (B) THE LICENSED PHYSICIAN'S PATIENT RECORD SHALL BE FULLY UPDATED
21 IN WRITING BY THE LICENSED PHARMACIST IN A TIMELY MANNER, AS PROVIDED IN
22 THE PHYSICIAN-PHARMACIST AGREEMENT.

23 12-6A-09.

24 NOTHING IN THIS SUBTITLE SUPERSEDES THE PROVISIONS OF § 5-902 OF THE
25 CRIMINAL LAW ARTICLE.

26 12-6A-10.

27 (A) SUBJECT TO SUBSECTION (B) OF THIS SECTION, THE BOARD OF
28 PHARMACY, TOGETHER WITH THE BOARD OF PHYSICIAN QUALITY ASSURANCE,
29 SHALL JOINTLY DEVELOP AND ADOPT REGULATIONS TO IMPLEMENT THE
30 PROVISIONS OF THIS SUBTITLE.

31 (B) THE REGULATIONS ADOPTED UNDER SUBSECTION (A) OF THIS SECTION
32 SHALL INCLUDE PROVISIONS THAT:

33 (1) DEFINE THE CRITERIA FOR PHYSICIAN-PHARMACIST AGREEMENTS;

34 (2) ESTABLISH GUIDELINES CONCERNING THE USE OF PROTOCOLS,
35 INCLUDING COMMUNICATION, DOCUMENTATION, AND OTHER RELEVANT FACTORS;
36 AND

1 (3) ESTABLISH A PROCEDURE TO ALLOW FOR THE APPROVAL,
2 MODIFICATION, CONTINUATION, OR DISAPPROVAL OF SPECIFIC PROTOCOLS BY THE
3 BOARD OF PHYSICIAN QUALITY ASSURANCE AND THE BOARD OF PHARMACY.

4 SECTION 2. AND BE IT FURTHER ENACTED, That the regulations required
5 by this Act shall be adopted within 6 months of the effective date of this Act.

6 SECTION 3. AND BE IT FURTHER ENACTED, That the Board of Pharmacy
7 and the Board of Physician Quality Assurance shall report to the Governor and, in
8 accordance with § 2-1246 of the State Government Article, the General Assembly on
9 or before October 1, 2006 on the effect of this Act and any recommendations for
10 legislative or regulatory action.

11 SECTION 4. AND BE IT FURTHER ENACTED, That the Department of
12 Health and Mental Hygiene shall conduct a study to assess the outcomes achieved by
13 drug therapy management agreements as provided for under this Act.

14 SECTION 5. AND BE IT FURTHER ENACTED, That this Act shall take effect
15 October 1, 2002. It shall remain effective for a period of 5 years ~~from the effective date~~
16 ~~of regulations adopted under this Act, and at the end of 5 years~~ *and 8 months and, at*
17 *the end of May 31, 2008* with no further action required by the General Assembly, this
18 Act shall be abrogated and of no further force and effect.