

HOUSE BILL 781

Unofficial Copy  
J2

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 \_\_\_\_\_

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.