

SENATE BILL 676

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2002 Regular Session
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By: **Senators Hollinger and Bromwell**
Introduced and read first time: February 1, 2002
Assigned to: Education, Health, and Environmental Affairs

Committee Report: Favorable with amendments
Senate action: Adopted
Read second time: March 19, 2002

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
15 therapy management contracts.

16 BY repealing and reenacting, without amendments,
17 Article - Health Occupations
18 Section 12-101(a), (i), and (m)
19 Annotated Code of Maryland
20 (2000 Replacement Volume and 2001 Supplement)

21 BY repealing and reenacting, with amendments,
22 Article - Health Occupations
23 Section 12-101(p)
24 Annotated Code of Maryland
25 (2000 Replacement Volume and 2001 Supplement)

1 BY adding to
2 Article - Health Occupations
3 Section 12-6A-01 through 12-6A-10, inclusive, to be under the new subtitle
4 "Subtitle 6A. Therapy Management Contracts"
5 Annotated Code of Maryland
6 (2000 Replacement Volume and 2001 Supplement)

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

9 **Article - Health Occupations**

10 12-101.

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

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

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

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

18 (i) Providing pharmaceutical care;

19 (ii) Compounding, dispensing, or distributing prescription drugs or
20 devices;

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

22 (iv) Monitoring prescriptions for prescription and nonprescription
23 drugs or devices;

24 (v) Providing information, explanation, or recommendations to
25 patients and health care practitioners about the safe and effective use of prescription
26 or nonprescription drugs or devices; [or]

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

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

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

1 SUBTITLE 6A. THERAPY MANAGEMENT CONTRACTS.

2 12-6A-01.

3 (A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS
4 INDICATED.

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

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

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

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

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

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

22 (I) ONE LICENSED PHARMACIST AND THE LICENSED
23 PHARMACIST'S DESIGNATED ALTERNATE LICENSED PHARMACISTS;

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

26 (III) ONE PATIENT RECEIVING CARE FROM A LICENSED PHYSICIAN
27 AND A LICENSED PHARMACIST PURSUANT TO A PHYSICIAN-PHARMACIST
28 AGREEMENT AND PROTOCOL UNDER THIS SUBTITLE.

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

33 12-6A-02.

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

1 12-6A-03.

2 (A) A LICENSED PHYSICIAN AND A LICENSED PHARMACIST WHO WISH TO
3 ENTER INTO THERAPY MANAGEMENT CONTRACTS SHALL HAVE A
4 PHYSICIAN-PHARMACIST AGREEMENT THAT IS APPROVED BY THE BOARD OF
5 PHARMACY AND THE BOARD OF PHYSICIAN QUALITY ASSURANCE.

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

9 (1) INADEQUATE TRAINING, EXPERIENCE, OR EDUCATION OF THE
10 PHYSICIANS OR PHARMACISTS TO IMPLEMENT THE PROTOCOL OR PROTOCOLS
11 SPECIFIED IN THE AGREEMENT; OR

12 (2) A FAILURE TO SATISFY REQUIREMENTS OF:

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

14 (II) REGULATIONS ESTABLISHED BY THE BOARD OF PHYSICIAN
15 QUALITY ASSURANCE AND THE BOARD OF PHARMACY ADOPTED UNDER THIS
16 SUBTITLE.

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

21 12-6A-04.

22 A PHARMACIST IS AUTHORIZED TO ENTER INTO A PHYSICIAN-PHARMACIST
23 AGREEMENT IF THE PHARMACIST:

24 (1) IS A LICENSED PHARMACIST;

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

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

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

32 12-6A-05.

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

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

4 12-6A-06.

5 (A) A PROTOCOL UNDER THIS SUBTITLE:

6 (1) MAY AUTHORIZE:

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

9 (II) THE ORDERING OF LABORATORY TESTS; AND

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

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

14 (B) A PROTOCOL SHALL PROHIBIT THE SUBSTITUTION OF A CHEMICALLY
15 DISSIMILAR DRUG PRODUCT BY THE PHARMACIST FOR THE PRODUCT PRESCRIBED
16 BY THE PHYSICIAN, UNLESS PERMITTED IN THE THERAPY MANAGEMENT CONTRACT.
17 12-6A-07.

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

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

25 (C) A THERAPY MANAGEMENT CONTRACT SHALL INCLUDE:

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

30 (2) NOTICE TO THE PATIENT INDICATING HOW THE PATIENT MAY
31 TERMINATE THE THERAPY MANAGEMENT CONTRACT;

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

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

3 (D) ANY PARTY TO THE THERAPY MANAGEMENT CONTRACT MAY TERMINATE
4 THE CONTRACT AT ANY TIME.

5 (E) FEES PAID TO THE BOARD OF PHYSICIAN QUALITY ASSURANCE AND
6 BOARD OF PHARMACY RELATED TO THERAPY MANAGEMENT SHALL BE
7 ESTABLISHED IN REGULATIONS.

8 12-6A-08.

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

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

14 12-6A-09.

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

17 12-6A-10.

18 (A) SUBJECT TO SUBSECTION (B) OF THIS SECTION, THE BOARD OF
19 PHARMACY, TOGETHER WITH THE BOARD OF PHYSICIAN QUALITY ASSURANCE,
20 SHALL JOINTLY DEVELOP AND ADOPT REGULATIONS TO IMPLEMENT THE
21 PROVISIONS OF THIS SUBTITLE.

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

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

25 (2) ESTABLISH GUIDELINES CONCERNING THE USE OF PROTOCOLS,
26 INCLUDING COMMUNICATION, DOCUMENTATION, AND OTHER RELEVANT FACTORS;
27 AND

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

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

33 SECTION 3. AND BE IT FURTHER ENACTED, That the Board of Pharmacy
34 and the Board of Physician Quality Assurance shall report to the Governor and, in
35 accordance with § 2-1246 of the State Government Article, the General Assembly on

1 or before October 1, 2006 on the effect of this Act and any recommendations for
2 legislative or regulatory action.

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

6 SECTION 5. AND BE IT FURTHER ENACTED, That this Act shall take effect
7 October 1, 2002. It shall remain effective for a period of 5 years ~~from the effective date~~
8 ~~of regulations adopted under this Act. At the end of 5 years and 6 months and, at the~~
9 end of March 31, 2008, with no further action required by the General Assembly, this
10 Act shall be abrogated and of no further force and effect.