
By: **Delegates Hammen, Bozman, Elliott, Klausmeier, and Sophocleus**
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Committee Report: Favorable with amendments
House action: Adopted
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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

1 Section 12-101(p)
2 Annotated Code of Maryland
3 (2000 Replacement Volume and 2001 Supplement)

4 BY adding to
5 Article - Health Occupations
6 Section 12-6A-01 through 12-6A-10, inclusive, to be under the new subtitle
7 "Subtitle 6A. Therapy Management Contracts"
8 Annotated Code of Maryland
9 (2000 Replacement Volume and 2001 Supplement)

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

12 **Article - Health Occupations**

13 12-101.

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

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

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

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

21 (i) Providing pharmaceutical care;

22 (ii) Compounding, dispensing, or distributing prescription drugs or
23 devices;

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

25 (iv) Monitoring prescriptions for prescription and nonprescription
26 drugs or devices;

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

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

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

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

3 SUBTITLE 6A. THERAPY MANAGEMENT CONTRACTS.

4 12-6A-01.

5 (A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS
6 INDICATED.

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

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

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

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

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

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

24 (I) ONE LICENSED PHARMACIST AND THE LICENSED
25 PHARMACIST'S DESIGNATED ALTERNATE LICENSED PHARMACISTS;

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

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

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

1 12-6A-02.

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

4 12-6A-03.

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

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

12 (1) INADEQUATE TRAINING, EXPERIENCE, OR EDUCATION OF THE
13 PHYSICIANS OR PHARMACISTS TO IMPLEMENT THE PROTOCOL OR PROTOCOLS
14 SPECIFIED IN THE AGREEMENT; OR

15 (2) A FAILURE TO SATISFY REQUIREMENTS OF:

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

17 (II) REGULATIONS ESTABLISHED BY THE BOARD OF PHYSICIAN
18 QUALITY ASSURANCE AND THE BOARD OF PHARMACY ADOPTED UNDER THIS
19 SUBTITLE.

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

24 12-6A-04.

25 A PHARMACIST IS AUTHORIZED TO ENTER INTO A PHYSICIAN-PHARMACIST
26 AGREEMENT IF THE PHARMACIST:

27 (1) IS A LICENSED PHARMACIST;

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

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

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

1 12-6A-05.

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

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

8 12-6A-06.

9 (A) A PROTOCOL UNDER THIS SUBTITLE:

10 (1) MAY AUTHORIZE:

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

13 (II) THE ORDERING OF LABORATORY TESTS; AND

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

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

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

21 12-6A-07.

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

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

29 (C) A THERAPY MANAGEMENT CONTRACT SHALL INCLUDE:

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

34 (2) NOTICE TO THE PATIENT INDICATING HOW THE PATIENT MAY
35 TERMINATE THE THERAPY MANAGEMENT CONTRACT;

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

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

6 (D) ANY PARTY TO THE THERAPY MANAGEMENT CONTRACT MAY TERMINATE
7 THE CONTRACT AT ANY TIME.

8 (E) FEES PAID TO THE BOARD OF PHYSICIAN QUALITY ASSURANCE AND
9 BOARD OF PHARMACY RELATED TO THERAPY MANAGEMENT SHALL BE
10 ESTABLISHED IN REGULATIONS.

11 12-6A-08.

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

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

17 12-6A-09.

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

20 12-6A-10.

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

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

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

28 (2) ESTABLISH GUIDELINES CONCERNING THE USE OF PROTOCOLS,
29 INCLUDING COMMUNICATION, DOCUMENTATION, AND OTHER RELEVANT FACTORS;
30 AND

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

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

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

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

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