
By: **Senator Bromwell**

Introduced and read first time: February 8, 2001

Assigned to: Rules

A BILL ENTITLED

1 AN ACT concerning

2 **Health Care - Therapy Management Agreements and Cooperative**
3 **Procedures**

4 FOR the purpose of authorizing certain licensed pharmacists to enter into therapy
5 management agreements with certain licensed health care practitioners for
6 certain purposes; providing that a therapy management agreement may not
7 authorize cooperative procedures that exceed certain scopes of practice;
8 establishing the types of cooperative procedures that a therapy management
9 agreement may involve; providing that a therapy management agreement may
10 only apply to certain conditions; prohibiting the performance of a cooperative
11 procedure without a patient's consent; providing that a licensed pharmacist who
12 deviates from a therapy management agreement is in violation of a certain
13 provision of law under certain circumstances; requiring the Board of Pharmacy
14 to jointly develop and adopt certain regulations with certain other licensing
15 boards; providing that a therapy management agreement may not be considered
16 effective until 90 days after the adoption of certain regulations; requiring the
17 Board of Pharmacy to make a certain report to the Governor and to the General
18 Assembly in a certain manner by a certain date; providing for the construction of
19 certain portions of this Act; providing for the termination of this Act; defining
20 certain terms; altering a certain definition; and generally relating to therapy
21 management agreements and cooperative procedures.

22 BY adding to
23 Article - Health Occupations
24 Section 6A-101 through 6A-107, inclusive, to be under the new subtitle
25 "Subtitle 6A. Therapy Management Agreements"
26 Annotated Code of Maryland
27 (2000 Replacement Volume)

28 BY repealing and reenacting, with amendments,
29 Article - Health Occupations
30 Section 12-101(p)
31 Annotated Code of Maryland
32 (2000 Replacement Volume)

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

3 **Article - Health Occupations**

4 SUBTITLE 6A. THERAPY MANAGEMENT AGREEMENTS.

5 6A-101.

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

8 (B) "THERAPY MANAGEMENT AGREEMENT" MEANS A VOLUNTARY, WRITTEN
9 AGREEMENT BETWEEN A LICENSED PHARMACIST AND A LICENSED PHYSICIAN,
10 LICENSED DENTIST, OR LICENSED PODIATRIST THAT AUTHORIZES THE LICENSED
11 PHARMACIST TO PERFORM SPECIFIED COOPERATIVE PROCEDURES ON PATIENTS OF
12 THE PRACTITIONER.

13 (C) "COOPERATIVE PROCEDURE" MEANS A PROCEDURE THAT RELATES TO
14 TREATMENT OF A PATIENT UNDER CONDITIONS DEFINED UNDER A THERAPY
15 MANAGEMENT AGREEMENT TO IMPROVE PATIENT OUTCOMES.

16 (D) "LICENSED DENTIST" MEANS AN INDIVIDUAL WHO IS LICENSED TO
17 PRACTICE DENTISTRY UNDER TITLE 4 OF THIS ARTICLE.

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

20 (F) "LICENSED PODIATRIST" MEANS AN INDIVIDUAL WHO IS LICENSED TO
21 PRACTICE PODIATRY UNDER TITLE 16 OF THIS ARTICLE.

22 6A-102.

23 SUBJECT TO THE REGULATIONS ADOPTED UNDER THIS SUBTITLE, A LICENSED
24 PHARMACIST MAY ENTER INTO A THERAPY MANAGEMENT AGREEMENT WITH A
25 LICENSED PHYSICIAN, A LICENSED DENTIST, OR A LICENSED PODIATRIST.

26 6A-103.

27 (A) A THERAPY MANAGEMENT AGREEMENT MAY NOT AUTHORIZE
28 COOPERATIVE PROCEDURES THAT EXCEED THE SCOPE OF PRACTICE OF THE
29 PARTIES TO THE THERAPY MANAGEMENT AGREEMENT.

30 (B) A THERAPY MANAGEMENT AGREEMENT MAY ONLY AUTHORIZE
31 COOPERATIVE PROCEDURES INVOLVING:

32 (1) THE ADMINISTRATION, MODIFICATION, CONTINUATION, AND
33 DISCONTINUATION OF DRUG THERAPY UNDER WRITTEN, PATIENT-SPECIFIC
34 PROTOCOLS;

1 (2) THE ORDERING OF LABORATORY TESTS; AND

2 (3) OTHER PATIENT CARE MANAGEMENT MEASURES RELATED TO
3 MONITORING OR IMPROVING THE OUTCOMES OF DRUG OR DEVICE THERAPY.

4 (C) A THERAPY MANAGEMENT AGREEMENT MAY ONLY APPLY TO
5 CONDITIONS:

6 (1) FOR WHICH PROTOCOLS EXIST THAT ARE CLINICALLY ACCEPTED AS
7 THE STANDARD OF CARE; OR

8 (2) THAT ARE APPROVED UNDER THE REGULATIONS ADOPTED UNDER
9 THIS SUBTITLE.

10 6A-104.

11 A COOPERATIVE PROCEDURE MAY NOT BE PERFORMED WITHOUT THE
12 CONSENT OF THE PATIENT.

13 6A-105.

14 (A) NOTHING IN THIS SUBTITLE MAY BE CONSTRUED TO REQUIRE A PATIENT
15 TO CONSENT TO A COOPERATIVE PROCEDURE.

16 (B) NOTHING IN THIS SUBTITLE MAY BE CONSTRUED TO REQUIRE A
17 LICENSED PHYSICIAN, A LICENSED DENTIST, OR A LICENSED PODIATRIST TO ENTER
18 INTO A THERAPY MANAGEMENT AGREEMENT WITH A LICENSED PHARMACIST.

19 (C) NOTHING IN THIS SUBTITLE MAY BE CONSTRUED TO SUPERSEDE THE
20 PROVISIONS OF ARTICLE 27, § 288(C) OF THE CODE.

21 6A-106.

22 A LICENSED PHARMACIST WHO DEVIATES FROM THE TERMS OF A THERAPY
23 MANAGEMENT AGREEMENT IS IN VIOLATION OF:

24 (1) § 14-601 OF THIS ARTICLE, IF THE DEVIATION IS AN ACT THAT MAY
25 ONLY BE LAWFULLY PERFORMED BY A LICENSED PHYSICIAN;

26 (2) § 4-601 OF THIS ARTICLE, IF THE DEVIATION IS AN ACT THAT MAY
27 ONLY BE LAWFULLY PERFORMED BY A LICENSED DENTIST; OR

28 (3) § 16-501 OF THIS ARTICLE, IF THE DEVIATION IS AN ACT THAT MAY
29 ONLY BE LAWFULLY PERFORMED BY A LICENSED PODIATRIST.

30 6A-107.

31 (A) SUBJECT TO SUBSECTION (B) OF THIS SECTION, THE BOARD OF
32 PHARMACY, TOGETHER WITH THE RESPECTIVE LICENSING BOARDS, SHALL JOINTLY
33 DEVELOP AND ADOPT REGULATIONS TO IMPLEMENT THE PROVISIONS OF THIS
34 SUBTITLE.

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

3 (1) DEFINE THOSE LICENSED PHARMACISTS WHO ARE ELIGIBLE, BASED
4 ON EDUCATION, TRAINING, AND OTHER RELEVANT CRITERIA, TO ENTER INTO
5 THERAPY MANAGEMENT AGREEMENTS;

6 (2) FACILITATE THE DEVELOPMENT AND IMPLEMENTATION OF SAFE
7 AND EFFECTIVE THERAPY MANAGEMENT AGREEMENTS BETWEEN THE
8 APPROPRIATE LICENSED PRACTITIONERS AND LICENSED PHARMACISTS;

9 (3) ESTABLISH GUIDELINES CONCERNING THE USE OF PROTOCOLS;
10 AND

11 (4) ESTABLISH A PROCEDURE TO ALLOW FOR THE APPROVAL OR
12 DISAPPROVAL OF SPECIFIC PROTOCOLS BY THE BOARD OF PHARMACY AND THE
13 RELEVANT LICENSING BOARD IF A LICENSED PHYSICIAN, A LICENSED DENTIST, A
14 LICENSED PODIATRIST, OR A LICENSED PHARMACIST REQUESTS A REVIEW.

15 12-101.

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 AGREEMENT, 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.

33 SECTION 2. AND BE IT FURTHER ENACTED, That a therapy management
34 agreement may not be considered effective until 90 days after the initial adoption of
35 the regulations required under this Act.

1 SECTION 3. AND BE IT FURTHER ENACTED, That the Board of Pharmacy
2 shall, with the input of the respective licensing boards, report to the Governor and, in
3 accordance with § 2-1246 of the State Government Article, the General Assembly on
4 or before December 1, 2004, on the effect of this Act and any recommendations for
5 legislative or regulatory action.

6 SECTION 4. AND BE IT FURTHER ENACTED, That this Act shall take effect
7 October 1, 2001. It shall remain effective for a period of 4 years and, at the end of
8 September 30, 2005, with no further action required by the General Assembly, this
9 Act shall be abrogated and of no further force and effect.