
By: **Delegate Owings**

Introduced and read first time: February 13, 1998

Assigned to: Environmental Matters

A BILL ENTITLED

1 AN ACT concerning

2 **State Board of Pharmacy - Collaborative Drug Therapy Management**

3 FOR the purpose of authorizing a licensed pharmacist to enter into a collaborative
4 practice agreement with a licensed physician, licensed dentist, or licensed
5 podiatrist under certain circumstances; specifying certain requirements that an
6 applicant who seeks to enter into a collaborative practice agreement must meet;
7 requiring the Board to approve or deny proposed collaborative practice
8 agreements; providing for the approval and renewal of collaborative practice
9 agreements; authorizing certain licensed pharmacists to perform certain
10 services; specifying the contents for collaborative practice agreements; requiring
11 a participating pharmacist to meet certain requirements before engaging in an
12 activity under a collaborative practice agreement; defining certain terms;
13 altering certain other terms; and generally relating to collaborative practice
14 agreements.

15 BY repealing and reenacting, without amendments,
16 Article - Health Occupations
17 Section 12-101(a)
18 Annotated Code of Maryland
19 (1994 Replacement Volume and 1997 Supplement)

20 BY repealing and reenacting, with amendments,
21 Article - Health Occupations
22 Section 12-101(e) and (p) and 12-313(b)(14), (27), and (28)
23 Annotated Code of Maryland
24 (1994 Replacement Volume and 1997 Supplement)

25 BY adding to
26 Article - Health Occupations
27 Section 12-313(b)(29) and 12-508
28 Annotated Code of Maryland
29 (1994 Replacement Volume and 1997 Supplement)

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 12-101.

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

6 (e) (1) "Device" means a device used in the diagnosis, treatment, or
7 prevention of disease.

8 (2) "Device" does not include any:

9 (i) Surgical or dental instrument;

10 (ii) Physical OR OCCUPATIONAL therapy equipment;

11 (iii) X-ray apparatus; or

12 (iv) Component part or accessory of any of these items.

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

15 (i) Providing pharmaceutical care;

16 (ii) Compounding, dispensing, or distributing prescription drugs or
17 devices;

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

19 (iv) Monitoring [prescriptions for prescription and nonprescription
20 drugs or devices] A PATIENT'S DRUG OR DEVICE THERAPY BY:

21 1. OBTAINING AND REVIEWING DATA PERTINENT TO A
22 PATIENT'S DRUG OR DEVICE THERAPY; AND

23 2. EVALUATING A PATIENT'S RESPONSE TO DRUG OR DEVICE
24 THERAPY;

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

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

30 (VII) UNDER § 12-508 OF THIS TITLE, PROVIDING DRUG THERAPY
31 MANAGEMENT IN ACCORDANCE WITH A COLLABORATIVE PRACTICE AGREEMENT.

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 12-313.

4 (b) Subject to the hearing provisions of § 12-315 of this subtitle, the Board, on
5 the affirmative vote of a majority of its members then serving, may deny a license to
6 any applicant, reprimand any licensee, place any licensee on probation, or suspend or
7 revoke a license if the applicant or licensee:

8 (14) [Dispenses] EXCEPT WHEN DISPENSING A DRUG OR DEVICE IN
9 ACCORDANCE WITH A COLLABORATIVE PRACTICE AGREEMENT UNDER § 12-508 OF
10 THIS TITLE, DISPENSES any drug, device, or diagnostic for which a prescription is
11 required without a written, oral, or electronically transmitted prescription from an
12 authorized prescriber;

13 (27) Provides or causes to be provided confidential patient information to
14 any person without first having obtained the patient's consent, as required by §
15 12-403(b)(13) of this title and by Title 4, Subtitle 3 of the Health - General Article;
16 [or]

17 (28) Fails to cooperate with a lawful investigation conducted by the Board
18 or the Division of Drug Control; OR

19 (29) IF ENGAGED IN A COLLABORATIVE PRACTICE AGREEMENT UNDER §
20 12-508 OF THIS TITLE, FAILS TO COMPLY WITH ANY PROVISION SPECIFIED IN THE
21 COLLABORATIVE PRACTICE AGREEMENT.

22 12-508.

23 (A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE MEANINGS
24 INDICATED.

25 (2) "COLLABORATIVE PRACTICE AGREEMENT" MEANS A WRITTEN
26 AGREEMENT THAT AUTHORIZES A LICENSED PHARMACIST TO ENGAGE IN DRUG
27 THERAPY MANAGEMENT THAT IS VOLUNTARILY ENTERED INTO BY:

28 (I) A LICENSED PHARMACIST; AND

29 (II) A LICENSED PHYSICIAN, LICENSED DENTIST, OR LICENSED
30 PODIATRIST.

31 (3) (I) "DRUG THERAPY MANAGEMENT" MEANS THE PERFORMANCE
32 OF SPECIFIC ACTS RELATED TO A PATIENT'S DRUG OR DEVICE THERAPY:

33 1. BY A PARTICIPATING PHARMACIST; AND

34 2. AS AUTHORIZED BY A PARTICIPATING PRESCRIBER
35 UNDER A COLLABORATIVE PRACTICE AGREEMENT.

36 (II) "DRUG THERAPY MANAGEMENT" INCLUDES:

- 1
2 HISTORY;
- 3
4 TESTS;
- 5
6 ASSESSMENTS; AND
- 7
8 OF DRUG THERAPY BY THE PARTICIPATING PRESCRIBER, IMPLEMENTING OR
9 ADJUSTING A PATIENT'S DRUG THERAPY.
1. COLLECTING AND REVIEWING A PATIENT'S DRUG USE
 2. ORDERING OR REVIEWING DRUG-RELATED LABORATORY
 3. ORDERING OR PERFORMING DRUG-RELATED PATIENT
 4. AFTER INITIAL ASSESSMENT, DIAGNOSIS, AND ORDERING

10 (4) "LICENSED DENTIST" MEANS A DENTIST WHO IS LICENSED BY THE
11 STATE BOARD OF DENTAL EXAMINERS TO PRACTICE DENTISTRY.

12 (5) "LICENSED PHYSICIAN" MEANS A PHYSICIAN WHO IS LICENSED BY
13 THE STATE BOARD OF PHYSICIAN QUALITY ASSURANCE TO PRACTICE MEDICINE.

14 (6) "LICENSED PODIATRIST" MEANS A PODIATRIST WHO IS LICENSED BY
15 THE STATE BOARD OF PODIATRIC MEDICAL EXAMINERS TO PRACTICE PODIATRY.

16 (7) "PARTICIPATING PHARMACIST" MEANS A LICENSED PHARMACIST
17 WHO PARTICIPATES IN A COLLABORATIVE PRACTICE AGREEMENT.

18 (8) "PARTICIPATING PRESCRIBER" MEANS A LICENSED PHYSICIAN,
19 LICENSED DENTIST, OR LICENSED PODIATRIST WHO PARTICIPATES IN A
20 COLLABORATIVE PRACTICE AGREEMENT.

21 (B) A LICENSED PHARMACIST MAY ENTER INTO A COLLABORATIVE PRACTICE
22 AGREEMENT WITH A LICENSED PHYSICIAN, LICENSED DENTIST, OR LICENSED
23 PODIATRIST IN ACCORDANCE WITH THIS SECTION.

24 (C) (1) TO ENTER INTO A COLLABORATIVE PRACTICE AGREEMENT UNDER
25 THIS SECTION, AN APPLICANT SHALL BE A LICENSED PHARMACIST AND MEET THE
26 REQUIREMENTS OF THIS SECTION.

27 (2) AN APPLICANT SHALL SUBMIT TO THE BOARD:

28 (I) AN APPLICATION ON A FORM PROVIDED BY THE BOARD;

29 (II) A COPY OF A PROPOSED COLLABORATIVE PRACTICE
30 AGREEMENT; AND

31 (III) DOCUMENTATION THAT THE PHARMACIST POSSESSES THE
32 KNOWLEDGE, SKILLS, AND ABILITIES NECESSARY TO ENGAGE IN THE ACTIVITIES
33 SPECIFIED IN THE AGREEMENT.

34 (3) IF AN APPLICANT SEEKS TO JOIN AN EXISTING COLLABORATIVE
35 PRACTICE AGREEMENT THAT HAS BEEN APPROVED BY THE BOARD, THE APPLICANT
36 SHALL:

1 (I) COMPLY WITH PARAGRAPH (2) OF THIS SUBSECTION; AND

2 (II) SUBMIT TO THE BOARD DOCUMENTATION THAT THE
3 PHARMACIST HAS OBTAINED THE CONSENT OF EACH PARTICIPATING PRESCRIBER
4 WHO IS A PARTY TO THE AGREEMENT.

5 (4) THE BOARD SHALL:

6 (I) REVIEW THE COLLABORATIVE PRACTICE AGREEMENT AND THE
7 SUPPORTING DOCUMENTATION; AND

8 (II) APPROVE OR DENY THE PROPOSED COLLABORATIVE PRACTICE
9 AGREEMENT WITHIN 35 DAYS AFTER RECEIVING THE APPLICATION.

10 (5) IF THE APPLICATION IS DENIED, THE BOARD SHALL STATE IN
11 WRITING THE REASONS FOR DENIAL.

12 (D) (1) UNLESS A COLLABORATIVE PRACTICE AGREEMENT IS RENEWED AS
13 PROVIDED IN PARAGRAPH (2) OF THIS SUBSECTION, THE COLLABORATIVE PRACTICE
14 AGREEMENT EXPIRES 2 YEARS AFTER ITS EFFECTIVE DATE.

15 (2) A PARTICIPATING PHARMACIST MAY RENEW A COLLABORATIVE
16 PRACTICE AGREEMENT BY:

17 (I) SUBMITTING A RENEWAL APPLICATION TO THE BOARD ON A
18 FORM PROVIDED BY THE BOARD;

19 (II) PROVIDING THE BOARD WITH A COPY OF THE COLLABORATIVE
20 PRACTICE AGREEMENT AND DOCUMENTATION OF THE PARTICIPATING
21 PHARMACIST'S KNOWLEDGE, SKILLS, AND ABILITIES; AND

22 (III) OBTAINING BOARD APPROVAL.

23 (3) THE BOARD SHALL:

24 (I) REVIEW THE RENEWAL APPLICATION AND SUPPORTING
25 DOCUMENTATION; AND

26 (II) APPROVE OR DENY THE PROPOSED RENEWAL WITHIN 35 DAYS
27 AFTER RECEIPT.

28 (4) IF A RENEWAL APPLICATION IS DENIED, THE BOARD SHALL STATE IN
29 WRITING THE REASONS FOR THE DENIAL.

30 (E) TO BE APPROVED BY THE BOARD, A COLLABORATIVE PRACTICE
31 AGREEMENT:

32 (1) SHALL BE IN WRITING;

33 (2) SHALL BE SIGNED BY:

1 (I) EACH PARTICIPATING PHARMACIST AND EACH PARTICIPATING
2 PRESCRIBER; OR

3 (II) EACH PARTICIPATING PHARMACIST AND A DESIGNEE OF THE
4 GOVERNING BODY OF A HOSPITAL AS DEFINED IN § 19-301 OF THE HEALTH -
5 GENERAL ARTICLE, ON BEHALF OF EACH PARTICIPATING PRESCRIBER;

6 (3) IF SIGNED BY A DESIGNEE OF THE GOVERNING BODY OF A HOSPITAL
7 AS DEFINED BY § 19-301 OF THE HEALTH - GENERAL ARTICLE, SHALL SPECIFY THE
8 METHOD TO BE USED TO ENSURE THAT EACH PARTICIPATING PRESCRIBER WILL
9 PARTICIPATE IN THE COLLABORATIVE PRACTICE AGREEMENT VOLUNTARILY;

10 (4) SHALL REQUIRE THAT A PARTICIPATING PHARMACIST WHO
11 ENGAGES IN AN ACTIVITY UNDER THE COLLABORATIVE PRACTICE AGREEMENT
12 REPORT THE ACTIVITY TO THE PARTICIPATING PRESCRIBER WITHIN 7 DAYS AFTER
13 ANY ACTION SO THAT THE INFORMATION MAY BE INCLUDED IN THE PARTICIPATING
14 PRESCRIBER RECORD FOR THE PATIENT;

15 (5) SHALL GRANT A PARTICIPATING PHARMACIST OR PARTICIPATING
16 PRESCRIBER THE RIGHT TO WITHDRAW FROM THE COLLABORATIVE PRACTICE
17 AGREEMENT AT ANY TIME AFTER GIVING REASONABLE NOTICE IN WRITING TO ALL
18 OTHER PARTICIPATING PHARMACISTS AND PARTICIPATING PRESCRIBERS;

19 (6) SHALL SPECIFY THE METHOD TO OBTAIN A PATIENT'S INFORMED
20 CONSENT TO BEING TREATED UNDER THE COLLABORATIVE PRACTICE AGREEMENT;

21 (7) SHALL ESTABLISH A METHOD FOR ENSURING CONTINUITY OF
22 PATIENT CARE SERVICES DURING THE PARTICIPATING PHARMACIST'S ABSENCE;

23 (8) SHALL DESIGNATE THE DRUGS, DEVICES, DRUG OR DEVICE
24 CATEGORIES, DISEASE STATES, CATEGORIES OF DISEASE, OR CONDITIONS FOR
25 WHICH THE PARTICIPATING PHARMACIST IS ALLOWED TO PROVIDE DRUG THERAPY
26 MANAGEMENT; AND

27 (9) SHALL CONTAIN ANY OTHER INFORMATION THAT THE BOARD
28 REQUIRES.

29 (F) (1) A PHARMACIST WHO PROVIDES PHARMACY SERVICES FOR PATIENTS
30 OF A HOSPITAL, AS DEFINED IN § 19-301 OF THE HEALTH - GENERAL ARTICLE, OR
31 RESIDENTS OF A COMPREHENSIVE CARE OR EXTENDED CARE FACILITY, AS DEFINED
32 IN THE REGULATIONS OF THE DEPARTMENT OF HEALTH AND MENTAL HYGIENE,
33 MAY ENGAGE IN DRUG THERAPY MANAGEMENT AS SPECIFIED BY THE
34 PARTICIPATING PRESCRIBER IN THE COLLABORATIVE PRACTICE AGREEMENT.

35 (2) A PHARMACIST PROVIDING PHARMACY SERVICES TO PATIENTS
36 OUTSIDE OF A HOSPITAL, COMPREHENSIVE CARE FACILITY, OR EXTENDED CARE
37 FACILITY MAY ENGAGE IN DRUG THERAPY MANAGEMENT, IF THE DRUG THERAPY
38 MANAGEMENT IS:

1 (I) SPECIFIED BY THE PARTICIPATING PRESCRIBER IN THE
2 COLLABORATIVE PRACTICE AGREEMENT; AND

3 (II) LIMITED TO:

4 1. ASTHMA;

5 2. DIABETES;

6 3. HYPERTENSION;

7 4. HYPERLIPIDEMIA;

8 5. ANTICOAGULATION THERAPY;

9 6. PAIN AND NAUSEA MANAGEMENT; OR

10 7. ANY OTHER DISEASE STATE OR DRUG OR DEVICE
11 CATEGORY THAT THE BOARD DEEMS APPROPRIATE.

12 (G) BEFORE ENGAGING IN DRUG THERAPY MANAGEMENT, UNDER A
13 COLLABORATIVE PRACTICE AGREEMENT, A PARTICIPATING LICENSED PHARMACIST
14 SHALL:

15 (1) ENSURE THAT THE PARTICIPATING PRESCRIBER HAS:

16 (I) PERFORMED AN INITIAL ASSESSMENT OF THE PATIENT;

17 (II) ESTABLISHED A DIAGNOSIS FOR THE PATIENT; AND

18 (III) ORDERED DRUG THERAPY FOR THE PATIENT;

19 (2) OBTAIN IN WRITING THE INFORMED CONSENT OF THE PATIENT OR
20 OF AN INDIVIDUAL WHO MAY ACT ON BEHALF OF THE PATIENT BEING TREATED
21 UNDER A COLLABORATIVE PRACTICE AGREEMENT; AND

22 (3) IN READILY RETRIEVABLE FORM:

23 (I) MAINTAIN A COPY OF THE COLLABORATIVE PRACTICE
24 AGREEMENT; AND

25 (II) OBTAIN AND RECORD DATA PERTINENT TO THE PATIENT'S
26 DRUG OR DEVICE THERAPY.

27 (H) (1) AT ANY TIME, THE BOARD:

28 (I) MAY CONDUCT PERIODIC QUALITY ASSURANCE REVIEWS OF A
29 COLLABORATIVE PRACTICE AGREEMENT; AND

30 (II) FOR GOOD CAUSE, MAY REVOKE APPROVAL OF THE
31 COLLABORATIVE PRACTICE AGREEMENT.

1 (2) IF APPROVAL OF A COLLABORATIVE PRACTICE AGREEMENT IS
2 REVOKED, THE BOARD SHALL STATE IN WRITING THE REASONS FOR THE
3 REVOCATION.

4 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
5 October 1, 1998.