
By: **Delegate Owings**
Introduced and read first time: February 13, 1998
Assigned to: Environmental Matters

Committee Report: Favorable with amendments
House action: Adopted
Read second time: March 27, 1998

CHAPTER _____

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; requiring the State Board of Pharmacy to establish one or more~~
9 ~~peer review committees; providing for the membership and duties of a peer~~
10 ~~review committee; requiring the Board to refer collaborating practice~~
11 ~~agreements to the peer review committee and to consider the recommendations~~
12 ~~of the peer review committee; requiring the Board to approve or deny proposed~~
13 ~~collaboration practice agreements within a certain time; providing for the~~
14 approval and renewal of collaborative practice agreements; authorizing certain
15 licensed pharmacists to perform certain services; specifying the contents for
16 collaborative practice agreements; requiring a participating pharmacist to meet
17 certain requirements before engaging in an activity under a collaborative
18 practice agreement; ~~prohibiting a person from coercing another person into~~
19 ~~entering a collaborative practice agreement; providing a penalty for certain~~
20 ~~violations of this Act; defining certain terms; altering certain other terms; and~~
21 generally relating to collaborative practice agreements.

22 BY repealing and reenacting, without amendments,
23 Article - Health Occupations
24 Section 12-101(a)
25 Annotated Code of Maryland
26 (1994 Replacement Volume and 1997 Supplement)

1 BY repealing and reenacting, with amendments,
 2 Article - Health Occupations
 3 Section 12-101(e) and (p) ~~and~~, 12-313(b)(14), (27), and (28), and 12-707(b)
 4 Annotated Code of Maryland
 5 (1994 Replacement Volume and 1997 Supplement)

6 BY adding to
 7 Article - Health Occupations
 8 Section 12-313(b)(29) ~~and 12-508, 12-508, and 12-705~~
 9 Annotated Code of Maryland
 10 (1994 Replacement Volume and 1997 Supplement)

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

13 **Article - Health Occupations**

14 12-101.

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

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

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

19 (i) Surgical or dental instrument;

20 (ii) Physical OR OCCUPATIONAL therapy equipment

21 ~~(iii)~~ (III) AUDIOLOGICAL EQUIPMENT;

22 ~~(iii)~~ (IV) X-ray apparatus; or

23 ~~(iv)~~ (V) Component part or accessory of any of these items.

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

26 (i) Providing pharmaceutical care;

27 (ii) Compounding, dispensing, or distributing prescription drugs or
 28 devices;

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

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

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

3 2. EVALUATING A PATIENT'S RESPONSE TO DRUG OR DEVICE
4 THERAPY;

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

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

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

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

14 12-313.

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

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

24 (27) Provides or causes to be provided confidential patient information to
25 any person without first having obtained the patient's consent, as required by §
26 12-403(b)(13) of this title and by Title 4, Subtitle 3 of the Health - General Article;
27 [or]

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

30 (29) IF ENGAGED IN A COLLABORATIVE PRACTICE AGREEMENT UNDER §
31 12-508 OF THIS TITLE, FAILS TO COMPLY WITH ANY PROVISION SPECIFIED IN THE
32 COLLABORATIVE PRACTICE AGREEMENT.

33 12-508.

34 (A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE MEANINGS
35 INDICATED.

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

4 (I) A LICENSED PHARMACIST; AND

5 (II) A LICENSED PHYSICIAN, LICENSED DENTIST, OR LICENSED
6 PODIATRIST.

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

9 1. BY A PARTICIPATING PHARMACIST; AND

10 2. AS AUTHORIZED BY A PARTICIPATING PRESCRIBER
11 UNDER A COLLABORATIVE PRACTICE AGREEMENT.

12 (II) "DRUG THERAPY MANAGEMENT" INCLUDES:

13 1. COLLECTING AND REVIEWING A PATIENT'S DRUG USE
14 HISTORY;

15 2. ORDERING OR REVIEWING DRUG-RELATED LABORATORY
16 TESTS;

17 3. ORDERING OR PERFORMING DRUG-RELATED PATIENT
18 ASSESSMENTS; AND

19 4. AFTER INITIAL ASSESSMENT, DIAGNOSIS, AND ORDERING
20 OF DRUG THERAPY BY THE PARTICIPATING PRESCRIBER, IMPLEMENTING OR
21 ADJUSTING A PATIENT'S DRUG THERAPY.

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

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

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

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

30 (8) "PARTICIPATING PRESCRIBER" MEANS A LICENSED PHYSICIAN,
31 LICENSED DENTIST, OR LICENSED PODIATRIST WHO PARTICIPATES IN A
32 COLLABORATIVE PRACTICE AGREEMENT.

33 (B) A LICENSED PHARMACIST MAY ENTER INTO A COLLABORATIVE PRACTICE
34 AGREEMENT WITH A LICENSED PHYSICIAN, LICENSED DENTIST, OR LICENSED
35 PODIATRIST IN ACCORDANCE WITH THIS SECTION.

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

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

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

6 (II) A COPY OF A PROPOSED COLLABORATIVE PRACTICE
7 AGREEMENT; AND

8 (III) DOCUMENTATION THAT THE PHARMACIST POSSESSES THE
9 KNOWLEDGE, SKILLS, AND ABILITIES NECESSARY TO ENGAGE IN THE ACTIVITIES
10 SPECIFIED IN THE AGREEMENT.

11 (3) IF AN APPLICANT SEEKS TO JOIN AN EXISTING COLLABORATIVE
12 PRACTICE AGREEMENT THAT HAS BEEN APPROVED BY THE BOARD, THE APPLICANT
13 SHALL:

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

15 (II) SUBMIT TO THE BOARD DOCUMENTATION THAT THE
16 PHARMACIST HAS OBTAINED THE CONSENT OF EACH PARTICIPATING PRESCRIBER
17 WHO IS A PARTY TO THE AGREEMENT.

18 ~~(4) THE BOARD SHALL:~~

19 ~~(I) REVIEW THE COLLABORATIVE PRACTICE AGREEMENT AND THE~~
20 ~~SUPPORTING DOCUMENTATION; AND~~

21 ~~(II) APPROVE OR DENY THE PROPOSED COLLABORATIVE PRACTICE~~
22 ~~AGREEMENT WITHIN 35 DAYS AFTER RECEIVING THE APPLICATION.~~

23 (4) (I) THE BOARD SHALL ESTABLISH ONE OR MORE PEER REVIEW
24 COMMITTEES.

25 (II) A PEER REVIEW COMMITTEE SHALL CONSIST OF THE
26 FOLLOWING MEMBERS APPOINTED BY EACH RESPECTIVE BOARD:

27 1. ONE MEMBER OF THE BOARD OF PHARMACY;

28 2. ONE MEMBER OF THE BOARD OF DENTAL EXAMINERS;

29 3. TWO MEMBERS OF THE BOARD OF PHYSICIAN QUALITY
30 ASSURANCE; AND

31 4. ONE MEMBER OF THE BOARD OF PODIATRIC MEDICAL
32 EXAMINERS.

33 (III) THE BOARD SHALL:

1 1. REFER TO A PEER REVIEW COMMITTEE ALL PROPOSED
2 COLLABORATIVE PRACTICE AGREEMENTS AND SUPPORTING DOCUMENTATION
3 RECEIVED BY THE BOARD FOR THE PEER REVIEW COMMITTEE'S REVIEW AND
4 RECOMMENDATIONS ON THE APPROPRIATENESS OF APPROVING THE PROPOSED
5 COLLABORATIVE PRACTICE AGREEMENT;

6 2. CONSIDER THE RECOMMENDATIONS OF THE PEER
7 REVIEW COMMITTEE; AND

8 3. APPROVE OR DENY THE PROPOSED COLLABORATIVE
9 PRACTICE AGREEMENT WITHIN 35 DAYS AFTER RECEIVING THE
10 RECOMMENDATIONS FROM THE PEER REVIEW COMMITTEE.

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

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

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

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

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

23 (III) OBTAINING BOARD APPROVAL.

24 (3) THE BOARD SHALL:

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

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

29 (I) REFER TO A PEER REVIEW COMMITTEE ESTABLISHED UNDER
30 SUBSECTION (C)(4) OF THIS SECTION ALL RENEWAL APPLICATIONS AND SUPPORTING
31 DOCUMENTATION RECEIVED BY THE BOARD FOR THE PEER REVIEW COMMITTEE'S
32 REVIEW AND RECOMMENDATIONS ON THE APPROPRIATENESS OF APPROVING THE
33 RENEWAL APPLICATION;

34 (II) CONSIDER THE RECOMMENDATIONS OF THE PEER REVIEW
35 COMMITTEE; AND

1 (III) APPROVE OR DENY THE RENEWAL APPLICATION WITHIN 35
2 DAYS AFTER RECEIVING THE RECOMMENDATIONS FROM THE PEER REVIEW
3 COMMITTEE.

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

6 (E) TO BE APPROVED BY THE BOARD, A COLLABORATIVE PRACTICE
7 AGREEMENT:

8 (1) SHALL BE IN WRITING;

9 (2) SHALL BE SIGNED BY:

10 (I) EACH PARTICIPATING PHARMACIST AND EACH PARTICIPATING
11 PRESCRIBER; OR

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

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

19 (4) SHALL REQUIRE THAT A PARTICIPATING PHARMACIST WHO
20 ENGAGES IN AN ACTIVITY UNDER THE COLLABORATIVE PRACTICE AGREEMENT
21 REPORT THE ACTIVITY TO THE PARTICIPATING PRESCRIBER WITHIN 7 DAYS AFTER
22 ANY ACTION SO THAT THE INFORMATION MAY BE INCLUDED IN THE PARTICIPATING
23 PRESCRIBER RECORD FOR THE PATIENT;

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

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

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

32 (8) SHALL DESIGNATE THE DRUGS, DEVICES, DRUG OR DEVICE
33 CATEGORIES, DISEASE STATES, CATEGORIES OF DISEASE, OR CONDITIONS FOR
34 WHICH THE PARTICIPATING PHARMACIST IS ALLOWED TO PROVIDE DRUG THERAPY
35 MANAGEMENT; AND

36 (9) SHALL CONTAIN ANY OTHER INFORMATION THAT THE BOARD
37 REQUIRES.

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

7 (2) A PHARMACIST PROVIDING PHARMACY SERVICES TO PATIENTS
8 OUTSIDE OF A HOSPITAL, COMPREHENSIVE CARE FACILITY, OR EXTENDED CARE
9 FACILITY MAY ENGAGE IN DRUG THERAPY MANAGEMENT, IF THE DRUG THERAPY
10 MANAGEMENT IS:

11 (I) SPECIFIED BY THE PARTICIPATING PRESCRIBER IN THE
12 COLLABORATIVE PRACTICE AGREEMENT; AND

13 (II) LIMITED TO:

- 14 1. ASTHMA;
- 15 2. DIABETES;
- 16 3. HYPERTENSION;
- 17 4. HYPERLIPIDEMIA;
- 18 5. ANTICOAGULATION THERAPY;
- 19 6. PAIN AND NAUSEA MANAGEMENT; OR
- 20 7. ANY OTHER DISEASE STATE OR DRUG OR DEVICE
21 CATEGORY THAT THE BOARD DEEMS APPROPRIATE AFTER REVIEW AND
22 RECOMMENDATION BY THE PEER REVIEW COMMITTEE ESTABLISHED UNDER
23 SUBSECTION (C)(4) OF THIS SECTION.

24 (G) BEFORE ENGAGING IN DRUG THERAPY MANAGEMENT, UNDER A
25 COLLABORATIVE PRACTICE AGREEMENT, A PARTICIPATING LICENSED PHARMACIST
26 SHALL:

27 (1) ENSURE THAT THE PARTICIPATING PRESCRIBER HAS:

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

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

30 (III) ORDERED DRUG THERAPY FOR THE PATIENT;

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

34 (3) IN READILY RETRIEVABLE FORM:

1 (I) MAINTAIN A COPY OF THE COLLABORATIVE PRACTICE
2 AGREEMENT; AND

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

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

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

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

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

13 12-705.

14 A PERSON MAY NOT COERCE ANOTHER PERSON TO ENTER INTO A
15 COLLABORATIVE PRACTICE AGREEMENT UNDER § 12-508 OF THIS TITLE.

16 12-707.

17 (b) A person who violates any provision of the following sections of this title is
18 guilty of a misdemeanor and on conviction is subject to a fine not exceeding \$1,000 or
19 imprisonment not exceeding 1 year or both:

20 (1) § 12-601 ("Manufacturing and packaging");

21 (2) § 12-602 ("Distribution permits");

22 (3) § 12-701 ("Practicing pharmacy without license");

23 (4) § 12-702 ("License obtained by false representation");

24 (5) § 12-703 ("Operating a pharmacy without permit"); [and]

25 (6) § 12-704 ("Misrepresentations")[:]; AND

26 (7) § 12-705 ("COERCING ANOTHER PERSON").

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

