

SENATE BILL 363

Unofficial Copy
J2

1998 Regular Session
8r1572
CF 8r1625

By: **Senator Collins**

Introduced and read first time: February 5, 1998

Assigned to: Economic and Environmental Affairs

A BILL ENTITLED

1 AN ACT concerning

2 **Licensed Physical Therapists and Licensed Physical Therapist Assistants -**
3 **Scope of Practice - Topical Pharmaceutical Agents**

4 FOR the purpose of authorizing licensed physical therapists and licensed physical
5 therapist assistants to apply to the skin of a patient certain topical
6 pharmaceutical agents in a certain manner and in accordance with certain
7 standards; including within the practice of physical therapy the procurement of
8 a topical pharmaceutical agent, but excluding that procurement from the
9 practice of limited physical therapy; providing that this Act may not be
10 construed to authorize certain physical therapy licensees to prescribe or to
11 dispense topical pharmaceutical agents; requiring the procurement of a topical
12 pharmaceutical agent to be made from a certain distribution permit holder;
13 specifying certain requirements concerning the use of a topical pharmaceutical
14 agent by certain physical therapy licensees; providing that the State Pharmacy
15 Act does not prohibit certain physical therapy licensees from applying a topical
16 pharmaceutical agent in accordance with certain requirements; authorizing
17 certain distribution permit holders to distribute a prescription drug or device to
18 a licensed physical therapist under certain conditions; requiring the State Board
19 of Physical Therapy Examiners, in consultation with the State Board of
20 Pharmacy, to adopt certain regulations; defining a certain term; and generally
21 relating to certain physical therapy licensees and topical pharmaceutical agents.

22 BY repealing and reenacting, without amendments,
23 Article - Health Occupations
24 Section 1-101 (a) and (d)
25 Annotated Code of Maryland
26 (1994 Replacement Volume and 1997 Supplement)

27 BY repealing and reenacting, with amendments,
28 Article - Health Occupations
29 Section 12-102, 12-602, and 13-101
30 Annotated Code of Maryland
31 (1994 Replacement Volume and 1997 Supplement)

1 BY adding to
2 Article - Health Occupations
3 Section 13-310.1
4 Annotated Code of Maryland
5 (1994 Replacement Volume and 1997 Supplement)

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

8 **Article - Health Occupations**

9 1-101.

10 (a) In this article the following words have the meanings indicated.

11 (d) "Department" means the Department of Health and Mental Hygiene.

12 12-102.

13 (a) (1) In this section the following terms have the meanings indicated.

14 (2) "In the public interest" means the dispensing of drugs or devices by a
15 licensed dentist, physician, or podiatrist to a patient when a pharmacy is not
16 conveniently available to the patient.

17 (3) "Personally preparing and dispensing" means that the licensed
18 dentist, physician, or podiatrist:

19 (i) Is physically present on the premises where the prescription is
20 filled; and

21 (ii) Performs a final check of the prescription before it is provided to
22 the patient.

23 (b) This title does not limit the right of an individual to practice a health
24 occupation that the individual is authorized to practice under this article.

25 (c) This title does not prohibit:

26 (1) A licensed veterinarian from personally preparing and dispensing the
27 veterinarian's prescriptions;

28 (2) A licensed dentist, physician, or podiatrist from personally preparing
29 and dispensing the dentist's, physician's, or podiatrist's prescriptions when:

30 (i) The dentist, physician, or podiatrist:

31 1. Has applied to the board of licensure in this State which
32 licensed the dentist, physician, or podiatrist;

- 1 2. Has demonstrated to the satisfaction of that board that
 2 the dispensing of prescription drugs or devices by the dentist, physician, or podiatrist
 3 is in the public interest; and
- 4 3. Has received a written permit from that board to dispense
 5 prescription drugs or devices except that a written permit is not required in order to
 6 dispense starter dosages or samples without charge;
- 7 (ii) The person for whom the drugs or devices are prescribed is a
 8 patient of the prescribing dentist, physician, or podiatrist;
- 9 (iii) The dentist, physician, or podiatrist does not have a substantial
 10 financial interest in a pharmacy; and
- 11 (iv) The dentist, physician, or podiatrist:
- 12 1. Complies with the labeling requirements of § 12-505 of
 13 this title;
- 14 2. Records the dispensing of the prescription drug or device
 15 on the patient's chart;
- 16 3. Allows the Division of Drug Control to enter and inspect
 17 the dentist's, physician's, or podiatrist's office at all reasonable hours;
- 18 4. Except for starter dosages or samples without charge,
 19 provides the patient with a written prescription, maintains prescription files in
 20 accordance with § 12-403(b)(13) of this title, and maintains a separate file for
 21 Schedule II prescriptions;
- 22 5. Does not direct patients to a single pharmacist or
 23 pharmacy IN ACCORDANCE WITH § 12-403(b)(8) of this title; and
- 24 6. Does not receive remuneration for referring patients to a
 25 pharmacist or pharmacy; or
- 26 (3) A hospital-based clinic from dispensing prescriptions to its patients.
- 27 (d) This title does not prohibit:
- 28 (1) A licensed veterinarian from personally dispensing a drug or device
 29 sample to a patient of the veterinarian; or
- 30 (2) A licensed dentist, licensed physician, or licensed podiatrist from
 31 personally dispensing a drug or device sample to a patient of the licensed dentist,
 32 licensed physician, or licensed podiatrist if:
- 33 (i) The sample complies with the labeling requirements of §
 34 12-505 of this title;
- 35 (ii) No charge is made for the sample; and

1 (iii) The authorized prescriber enters an appropriate record in the
2 patient's chart.

3 (e) (1) This title does not prohibit a dentist, physician, or podiatrist from
4 administering a prescription drug or device in the course of treating a patient.

5 (2) For the purposes of paragraph (1) of this subsection, "administering"
6 means the direct introduction of a single dosage of a drug or device at a given time,
7 whether by injection or other means, and whether in liquid, tablet, capsule, or other
8 form.

9 (f) (1) This title does not prohibit a dentist, physician, or podiatrist from
10 personally dispensing a starter dosage of a prescription drug or device to a patient of
11 the dentist, physician, or podiatrist, provided that:

12 (i) The starter dosage complies with the labeling requirements of §
13 12-505 of this title;

14 (ii) No charge is made for the starter dosage; and

15 (iii) The dentist, physician, or podiatrist enters an appropriate
16 record on the patient's chart.

17 (2) For the purposes of paragraph (1) of this subsection, "starter dosage"
18 means an amount of drug or device sufficient to begin therapy:

19 (i) Of short duration of 72 hours or less; or

20 (ii) Prior to obtaining a larger quantity of the drug or device to
21 complete the therapy.

22 (g) This title does not prohibit a dentist, physician, or podiatrist from
23 dispensing a prescription drug or device in the course of treating a patient:

24 (1) At a medical facility or clinic that specializes in the treatment of
25 medical cases reimbursable through workers' compensation insurance;

26 (2) At a medical facility or clinic that is operated on a nonprofit basis;

27 (3) At a health center that operates on a campus of an institution of
28 higher education; or

29 (4) At a public health facility, a medical facility under contract with a
30 State or local health department, or a facility funded with public funds.

31 (H) THIS TITLE DOES NOT PROHIBIT A LICENSED PHYSICAL THERAPIST OR A
32 LICENSED PHYSICAL THERAPIST ASSISTANT FROM APPLYING TO THE SKIN A
33 TOPICAL PHARMACEUTICAL AGENT IN THE COURSE OF TREATING A PATIENT IN
34 ACCORDANCE WITH TITLE 13 OF THIS ARTICLE.

35 [(h)] (I) This title does not limit the right of a general merchant to sell:

- 1 (1) Any nonprescription drug or device;
- 2 (2) Any commonly used household or domestic remedy; or
- 3 (3) Any farm remedy or ingredient for a spraying solution, in bulk or
4 otherwise.

5 [(i)] (J) A dentist, physician, or podiatrist who fails to comply with the
6 provisions of this section governing the dispensing of prescription drugs or devices
7 shall:

- 8 (1) Have the dispensing permit revoked; and
- 9 (2) Be subject to disciplinary actions by the appropriate licensing board.
10 12-602.

11 (a) (1) In this section, the following words have the meanings indicated.

12 (2) "Distribution permit" means a permit issued by the Board under this
13 section to distribute prescription drugs or devices into, out of, or within the State as a
14 distributor, jobber, manufacturer, or wholesaler, wherever located.

15 (3) "Prescription drugs or devices" means any drug or device that,
16 because of its toxicity or other potential for harmful effect, the method of its use, or
17 the collateral measures necessary for its use, is required by federal law to bear a
18 cautionary label warning against dispensing without a prescription or is designated
19 by the Department as not safe for use except under the supervision of a practitioner
20 licensed to administer drugs or devices of this nature.

21 (b) This section does not affect any person while distributing:

- 22 (1) Feed for livestock or poultry;
- 23 (2) Fertilizers;
- 24 (3) Fungicides;
- 25 (4) Insecticide;
- 26 (5) Land plaster;
- 27 (6) Lime;
- 28 (7) Seeds; or
- 29 (8) Devices, drugs, or supplies of any kind for the treatment, care, or cure
30 of farm animals.

1 (c) A person shall hold a distribution permit issued by the Board before the
2 person may distribute prescription drugs or devices as a distributor, jobber,
3 manufacturer, or wholesaler.

4 (d) To qualify for a distribution permit, an applicant shall:

5 (1) Satisfy the Board that the applicant will distribute prescription
6 drugs or devices in compliance with the restrictions specified in subsection (e) of this
7 section; and

8 (2) Comply with any pertinent regulations adopted under subsection (i)
9 of this section.

10 (e) A distribution permit holder may distribute prescription drugs or devices
11 only:

12 (1) To the following persons:

13 (i) An authorized prescriber;

14 (ii) A pharmacy permit holder;

15 (iii) A distribution permit holder; [or]

16 (IV) A LICENSED PHYSICAL THERAPIST UNDER THE CONDITIONS
17 SPECIFIED IN § 13-310.1 OF THIS ARTICLE; OR

18 [(iv)] (V) Any other person approved by the Board; and

19 (2) In compliance with any rules and regulations adopted under this
20 section.

21 (f) To apply for a distribution permit, an applicant shall:

22 (1) Submit an application to the Board on the form that the Board
23 provides; and

24 (2) Pay to the Board an application fee set by the Board.

25 (g) The Board shall issue a distribution permit to any applicant who meets the
26 requirements of this section.

27 (h) A distribution permit issued under this section authorizes the distribution
28 permit holder to distribute prescription drugs or devices as a distributor, jobber,
29 manufacturer, or wholesaler while the distribution permit is effective.

30 (i) To protect the public health and safety, the Board may adopt rules and
31 regulations regarding the distribution of prescription drugs or devices including
32 regulations regarding:

1 (1) Qualifications and information required from an applicant seeking
2 issuance or renewal of a distribution permit;

3 (2) Minimum requirements for the receipt, storage, and handling of
4 prescription drugs or devices, security precautions, quality control, recordkeeping,
5 and establishment of written procedures, policy, and responsibilities of personnel;

6 (3) The education and experience of personnel employed in positions
7 responsible for duties referenced in paragraph (2) of this subsection and generally
8 responsible for carrying out those duties that are subject to State licensure
9 requirements under this subtitle; and

10 (4) Disciplinary action to be taken against a permit holder who is
11 convicted of or pleads guilty or nolo contendere to a violation of State, federal, or local
12 drug laws or who violates regulations promulgated by the Board under this section.

13 (j) (1) A distribution permit expires on the December 31 after its effective
14 date, unless the distribution permit is renewed for a 1-year term as provided in this
15 subsection.

16 (2) At least 1 month before a distribution permit expires, the Board shall
17 send to the distribution permit holder, by first-class mail to the last known address of
18 the distribution permit holder, a renewal notice that contains a statement of:

19 (i) The date on which the current distribution permit expires;

20 (ii) The date by which the renewal application must be received by
21 the Board for the renewal to be issued and mailed before the distribution permit
22 expires; and

23 (iii) The amount of the renewal fee.

24 (3) Before a distribution permit expires, a distribution permit holder
25 periodically may renew it for an additional 1-year term, if the distribution permit
26 holder:

27 (i) Otherwise is entitled to a distribution permit;

28 (ii) Pays to the Board a renewal fee set by the Board; and

29 (iii) Submits to the Board a renewal application on the form that the
30 Board requires.

31 (4) The Board shall renew the distribution permit of each distribution
32 permit holder who meets the requirements of this section and any regulation adopted
33 under this section.

34 (k) Each distribution permit shall be displayed conspicuously in the place for
35 which it is issued.

36 (l) A distribution permit is not transferable.

1 (m) Subject to any other restriction provided by law, a person may not
2 purchase or obtain any prescription drugs or devices unless the drug or device is
3 obtained from a distribution permit holder, a licensed pharmacist, or an authorized
4 prescriber.

5 (n) A person may not violate any rule or regulation adopted under this section.

6 (o) A distribution permit is void on conviction of the distribution permit holder
7 for any violation of:

8 (1) This section; or

9 (2) Any rule or regulation adopted by the Board under this section.

10 13-101.

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

12 (b) "Board" means the State Board of Physical Therapy Examiners.

13 (c) "License" means, unless the context requires otherwise, a license issued by
14 the Board to practice:

15 (1) Physical therapy; or

16 (2) Limited physical therapy.

17 (d) "Licensed physical therapist" means, unless the context requires
18 otherwise, a physical therapist who is licensed by the Board to practice physical
19 therapy.

20 (e) "Licensed physical therapist assistant" means, unless the context requires
21 otherwise, a physical therapist assistant who is licensed by the Board to practice
22 limited physical therapy.

23 (f) "Physical therapist" means an individual, licensed by the State Board of
24 Physical Therapy Examiners, who practices physical therapy and who has passed the
25 national physical therapy licensing examination administered or accepted by the
26 Board.

27 (g) "Physical therapist assistant" means an individual who practices limited
28 physical therapy and who has passed the national physical therapy licensing
29 examination administered or accepted by the Board.

30 (h) (1) "Practice limited physical therapy" means to practice the health
31 specialty concerned with:

32 (i) The prevention of disability in individuals; and

33 (ii) The physical rehabilitation of individuals with a congenital or
34 acquired disability.

1 (2) "Practice limited physical therapy" includes, except as provided in
2 paragraph (3) of this [subsection,] SUBSECTION:

3 (I) [administering] ADMINISTERING treatment with therapeutic
4 exercise, therapeutic massage, mechanical devices, or therapeutic agents that use the
5 physical, chemical, or other properties of air, water, electricity, sound, or radiant
6 energy; AND

7 (II) APPLYING TO THE SKIN TOPICAL PHARMACEUTICAL AGENTS IN
8 ACCORDANCE WITH § 13-310.1 OF THIS TITLE.

9 (3) "Practice limited physical therapy" does not include:

10 (i) Performing and interpreting tests and measurements of
11 neuromuscular and musculoskeletal functions to aid treatment;

12 (ii) Planning treatment programs that are based on test findings;
13 [or]

14 (III) THE PROCUREMENT OF A TOPICAL PHARMACEUTICAL AGENT;
15 OR

16 [(iii)] (IV) Using:

17 1. X rays;

18 2. Radioactive substances; or

19 3. Electricity for cauterization or surgery.

20 (i) (1) "Practice physical therapy" means to practice the health specialty
21 concerned with:

22 (i) The prevention of disability in individuals; and

23 (ii) The physical rehabilitation of individuals with a congenital or
24 acquired disability.

25 (2) "Practice physical therapy" includes:

26 (i) Performing an evaluation of the physical therapy needs of
27 individuals;

28 (ii) Performing and interpreting tests and measurements of
29 neuromuscular and musculoskeletal functions to aid treatment;

30 (iii) Planning treatment programs that are based on test findings;
31 [and]

32 (iv) Except as provided in paragraph (3) of this subsection,
33 administering treatment with therapeutic exercise, therapeutic massage, mechanical

1 devices, or therapeutic agents that use the physical, chemical, or other properties of
2 air, water, electricity, sound, or radiant energy; AND

3 (V) PROCURING AND APPLYING TO THE SKIN A TOPICAL
4 PHARMACEUTICAL AGENT IN ACCORDANCE WITH § 13-310.1 OF THIS TITLE.

5 (3) "Practice physical therapy" does not include using:

6 (i) X rays;

7 (ii) Radioactive substances; or

8 (iii) Electricity for cauterization or surgery.

9 (j) "Restricted license" means a license issued by the Board under and as
10 limited by § 13-314 of this title to practice physical therapy.

11 (k) "Temporary license" means a license issued by the Board under and as
12 limited by § 13-313 of this title to practice:

13 (1) Physical therapy; or

14 (2) Limited physical therapy.

15 13-310.1.

16 (A) THIS SECTION MAY NOT BE CONSTRUED TO AUTHORIZE A LICENSED
17 PHYSICAL THERAPIST OR PHYSICAL THERAPIST ASSISTANT TO PRESCRIBE FOR THE
18 USE OF A PATIENT, OR TO DISPENSE TO A PATIENT, A TOPICAL PHARMACEUTICAL
19 AGENT.

20 (B) IN THIS SECTION, "TOPICAL PHARMACEUTICAL AGENT" MEANS THE
21 FOLLOWING PRESCRIPTION DRUGS:

22 (1) AN ANTIBACTERIAL AGENT;

23 (2) A DEBRIDING AGENT;

24 (3) AN ANESTHETIC AGENT; AND

25 (4) AN ANTI-INFLAMMATORY AGENT.

26 (C) (1) A LICENSED PHYSICAL THERAPIST OR LICENSED PHYSICAL
27 THERAPIST ASSISTANT MAY APPLY TO THE SKIN A TOPICAL PHARMACEUTICAL
28 AGENT ONLY BY:

29 (I) DIRECT APPLICATION;

30 (II) IONTOPHORESIS; OR

31 (III) PHONOPHORESIS.

1 (2) A LICENSED PHYSICAL THERAPIST OR LICENSED PHYSICAL
2 THERAPIST ASSISTANT SHALL APPLY TO THE SKIN A TOPICAL PHARMACEUTICAL
3 AGENT IN ACCORDANCE WITH GENERALLY ACCEPTED PRACTICES AND THE
4 EDUCATIONAL TECHNIQUES IN USE AT SCHOOLS ACCREDITED BY THE COMMISSION
5 ON ACCREDITATION IN PHYSICAL THERAPY EDUCATION.

6 (D) A TOPICAL PHARMACEUTICAL AGENT PROCURED UNDER THIS SECTION
7 SHALL BE OBTAINED FROM A PERSON THAT HOLDS A DISTRIBUTION PERMIT ISSUED
8 UNDER § 12-602 OF THIS ARTICLE.

9 (E) TO USE A TOPICAL PHARMACEUTICAL AGENT UNDER THIS SECTION, A
10 LICENSED PHYSICAL THERAPIST OR A LICENSED PHYSICAL THERAPIST ASSISTANT
11 SHALL ENSURE THAT THE ORIGINAL LABEL OF THE MANUFACTURER:

12 (1) IS AFFIXED TO THE TOPICAL PHARMACEUTICAL AGENT; AND

13 (2) INCLUDES:

14 (I) THE NAME OF THE MANUFACTURER;

15 (II) THE NAME AND STRENGTH OF THE TOPICAL PHARMACEUTICAL
16 AGENT;

17 (III) THE LOT NUMBER; AND

18 (IV) THE EXPIRATION DATE OF THE TOPICAL PHARMACEUTICAL
19 AGENT.

20 (F) A LICENSED PHYSICAL THERAPIST OR A LICENSED PHYSICAL THERAPIST
21 ASSISTANT:

22 (1) SHALL HAVE APPROPRIATE DOCUMENTATION IN THE PATIENT'S
23 MEDICAL RECORD CONCERNING THE APPLICATION OF A TOPICAL PHARMACEUTICAL
24 AGENT; AND

25 (2) SHALL ALLOW THE OFFICE OF DRUG CONTROL OF THE
26 DEPARTMENT TO ENTER AND INSPECT THE OFFICE OF THE LICENSED PHYSICAL
27 THERAPIST OR THE LICENSED PHYSICAL THERAPIST ASSISTANT AT ALL
28 REASONABLE HOURS.

29 (G) IN CONSULTATION WITH THE STATE BOARD OF PHARMACY, THE BOARD
30 SHALL ADOPT REGULATIONS CONCERNING THE STORAGE OF TOPICAL
31 PHARMACEUTICAL AGENTS PROCURED UNDER THIS SECTION.

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