

CF 7r1966

By: Delegates McHale, Bozman, Elliott, and Donoghue

Introduced and read first time: February 3, 1997

Assigned to: Environmental Matters

Committee Report: Favorable with amendments

House action: Adopted

Read second time: March 11, 1997

CHAPTER ____

1 AN ACT concerning

2 **State Board of Pharmacy - Issuance of Permits - Dialysis Drugs and Devices**

3 FOR the purpose of altering certain provisions of law relating to the issuance of permits

4 by the State Board of Pharmacy to distribute dialysis drugs and devices to the homes

5 of dialysis patients and the distribution of dialysis drugs and devices to certain

6 individuals; altering certain definitions; providing for the effective date of this Act;

7 and generally relating to the issuance of permits by the State Board of Pharmacy to

8 distribute dialysis drugs and devices to the homes of dialysis patients.

9 BY repealing and reenacting, with amendments,

10 Article - Health Occupations

11 Section 12-603

12 Annotated Code of Maryland

13 (1994 Replacement Volume and 1996 Supplement)

14 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF

15 MARYLAND, That the Laws of Maryland read as follows:

16 **Article - Health Occupations**

17 12-603.

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

19 (2) "[Hemodialysis] DIALYSIS drugs and devices" means:

20 (i) Dialysate AND DIALYSIS SOLUTIONS;

21 (ii) Dialyzers, delivery systems, and their accessory equipment

22 NECESSARY TO ADMINISTER THESE PRODUCTS;

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1 (iii) Heparin;

2 (iv) Local anesthetics AND ANY OTHER DRUGS AND DEVICES
3 approved by the Board under subsection (g) of this section;

4 (v) Needles;

5 (vi) Syringes; and

6 (vii) Sterile sodium chloride [, 0.9%] AND STERILE POTASSIUM
7 CHLORIDE.

8 (3) "Home [hemodialysis] DIALYSIS distribution permit" means a permit
9 issued by the Board to distribute [hemodialysis] DIALYSIS drugs and devices to the
10 homes of [hemodialysis] DIALYSIS patients.

11 (b) (1) Except as provided under this subsection, a person shall hold a home
12 [hemodialysis] DIALYSIS distribution permit issued by the Board before the person may
13 distribute [hemodialysis] DIALYSIS drugs and devices to the home of a [hemodialysis]
14 DIALYSIS patient.

15 (2) A licensed pharmacist may distribute [hemodialysis] DIALYSIS drugs
16 and devices under this section without the home [hemodialysis] DIALYSIS distribution
17 permit otherwise required by this section.

18 (c) To qualify for a home [hemodialysis] DIALYSIS distribution permit, an
19 applicant shall satisfy the Board that the applicant will distribute [hemodialysis]
20 DIALYSIS drugs and devices in compliance with subsection (h) of this section.

21 (d) To apply for a home [hemodialysis] DIALYSIS distribution permit, an
22 applicant shall:

23 (1) Submit an application to the Board on the form that the Board requires;
24 and

25 (2) Pay to the Board a fee set by the Board.

26 (e) The Board shall issue a home [hemodialysis] DIALYSIS distribution permit to
27 any applicant who meets the requirements of this section.

28 (f) A home [hemodialysis] DIALYSIS distribution permit issued under this
29 section authorizes the home [hemodialysis] DIALYSIS distribution permit holder to
30 distribute [hemodialysis] DIALYSIS drugs and devices to the home of a [hemodialysis]
31 DIALYSIS patient while the home [hemodialysis] DIALYSIS distribution permit is
32 effective.

33 (g) (1) The Board may approve local anesthetics AND OTHER DRUGS AND
34 DEVICES for distribution as [hemodialysis] DIALYSIS drugs AND DEVICES under this
35 section.

36 (2) The Board may adopt rules and regulations to assure safe, proper, and
37 uninterrupted distribution of [hemodialysis] DIALYSIS drugs and devices, including rules
38 and regulations as to:

3

1 (i) Maintaining facilities that are adequate to assure proper security
2 and control of [hemodialysis] DIALYSIS drugs and devices;

3 (ii) Keeping records;

4 (iii) Labeling [hemodialysis] DIALYSIS drugs and devices;

5 (iv) Receipts AND RETURNS from patients for [hemodialysis]
6 DIALYSIS drugs and devices;

7 (v) Reports to the Board; and

8 (vi) Restrictions on specific [hemodialysis] DIALYSIS drugs or
9 devices, including limitations on the amounts that may be distributed.

10 (h) A person authorized to distribute [hemodialysis] DIALYSIS drugs and devices
11 under this section may distribute only [hemodialysis] DIALYSIS drugs and devices:

12 (1) That the Board, after consultation with the State Commission on Kidney
13 Disease, has approved as effective and safe for their intended use;

14 (2) Under supervision of a person who the Board considers qualified to
15 safeguard and protect the public health;

16 (3) To an individual:

17 (i) Who has [permanently] IRREVERSIBLY lost [the] function of
18 the individual's kidneys and requires regular treatment ~~with a kidney machine OR OTHER~~
19 ~~TREATMENT MODALITY TO SUSTAIN LIFE~~; and

20 (ii) Who has completed a full course of training in providing the
21 individual's own [hemodialysis] DIALYSIS treatment ~~{~~ GIVEN BY:

22 1. ~~Given~~ GIVEN by a A home dialysis training facility ~~}; and~~ ;
23 OR

24 2. ~~With another individual personally committed to the~~
25 ~~treatment of the individual who has permanently lost kidney function~~ AN END STAGE
26 RENAL DISEASE CLINIC CERTIFIED UNDER MEDICARE; and

27 (4) In compliance with the rules and regulations adopted by the Board
28 under this section.

29 (i) Subject to the Administrative Procedure Act, the Board may suspend or
30 revoke the home [hemodialysis] DIALYSIS distribution permit of any home
31 [hemodialysis] DIALYSIS distribution permit holder who fails to comply with subsection
32 (h) of this section.

33 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
34 June 1, 1997.

