

1 HB260
2 173246-1
3 By Representative Beech
4 RFD: Health
5 First Read: 18-FEB-16

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8 SYNOPSIS: This bill would exempt certain facilities
9 engaged solely in the distribution of dialysate,
10 drugs, or devices necessary to perform home renal
11 dialysis to patients with chronic kidney failure
12 from regulation by the Alabama State Board of
13 Pharmacy.

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15 A BILL
16 TO BE ENTITLED
17 AN ACT

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19 To add Section 34-23-77 to the Code of Alabama 1975,
20 to exempt certain facilities engaged solely in the
21 distribution of dialysate, drugs, or devices necessary to
22 perform home renal dialysis to patients with chronic kidney
23 failure from regulation by the Alabama State Board of
24 Pharmacy.

25 BE IT ENACTED BY THE LEGISLATURE OF ALABAMA:

26 Section 1. Section 34-23-77 is added to the Code of
27 Alabama 1975, to read as follows:

1 §34-23-77. A facility engaged solely in the
2 distribution of dialysate, drugs, or devices necessary to
3 perform home renal dialysis to patients with chronic kidney
4 failure, is exempt from regulation by the Alabama State Board
5 of Pharmacy provided all of the following criteria are
6 satisfied:

7 (1) The dialysate, drugs, or devices are approved or
8 cleared by the Food and Drug Administration, as required by
9 federal law.

10 (2) The dialysate, drugs, or devices are lawfully
11 held by a manufacturer, or the agent of a manufacturer, that
12 is properly registered with the board as a manufacturer or
13 wholesaler, or both.

14 (3) The dialysate, drugs, or devices are held and
15 delivered in their original, sealed packaging from the
16 manufacturing facility.

17 (4) The dialysate, drugs, or devices are delivered
18 only by the manufacturer, or the agent of the manufacturer,
19 and only upon receipt of the order of a physician.

20 (5) The manufacturer, or agent of the manufacturer,
21 delivers the dialysate, drugs, or devices directly to any of
22 the following:

23 a. A patient with chronic kidney failure, or his or
24 her designee, for self-administration by the patient of the
25 dialysis therapy.

1 b. A health care provider or institution for
2 administration or delivery of the dialysis therapy to a
3 patient with chronic kidney failure.

4 Section 2. This act shall become effective on the
5 first day of the third month following its passage and
6 approval by the Governor, or its otherwise becoming law.