

1 SB396  
2 173246-1  
3 By Senator Whatley  
4 RFD: Health and Human Services  
5 First Read: 07-APR-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

18  
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.