

HOUSE BILL REPORT

SHB 1675

As Passed House:

January 26, 2022

Title: An act relating to exempting a manufacturer of certain dialysate and dialysis devices used by home dialysis patients or a manufacturer's agent from the pharmacy practices act and legend drug act.

Brief Description: Exempting a manufacturer of certain dialysate and dialysis devices used by home dialysis patients or a manufacturer's agent from the pharmacy practices act and legend drug act.

Sponsors: House Committee on Health Care & Wellness (originally sponsored by Representatives Bateman, Maycumber, Leavitt, Graham, Dolan, Cody, Griffey and Riccelli).

Brief History:

Committee Activity:

Health Care & Wellness: 1/12/22, 1/19/22 [DPS].

Floor Activity:

Passed House: 1/26/22, 97-0.

Brief Summary of Substitute Bill

- Requires that pharmacy and legend drug regulations allow manufacturers and wholesalers to sell, possess, deliver, or dispense dialysis devices and related legend drugs directly to home dialysis patients.

HOUSE COMMITTEE ON HEALTH CARE & WELLNESS

Majority Report: The substitute bill be substituted therefor and the substitute bill do pass. Signed by 15 members: Representatives Cody, Chair; Bateman, Vice Chair; Schmick, Ranking Minority Member; Caldier, Assistant Ranking Minority Member; Bronoske, Davis, Harris, Macri, Maycumber, Riccelli, Rude, Simmons, Stonier, Tharinger and Ybarra.

This analysis was prepared by non-partisan legislative staff for the use of legislative members in their deliberations. This analysis is not part of the legislation nor does it constitute a statement of legislative intent.

Staff: Christopher Blake (786-7392).

Background:

Dialysis treats end-stage kidney failure by removing waste from a patient's blood when the kidneys are no longer able to perform the function. There are different types of dialysis, including hemodialysis and peritoneal dialysis. Hemodialysis removes blood from the body and filters it through a machine and returns it to the body. Hemodialysis is usually performed in a health care setting, but may be done at home. Peritoneal dialysis filters blood by sending a dialysis solution, called dialysate, through a catheter into part of the abdomen where it filters waste products from the blood through the lining of the abdomen. Peritoneal dialysis is frequently performed at home by the patient or the patient's caregiver.

Medicare-approved home dialysis centers or facilities operating Medicare-approved home dialysis programs may sell, deliver, possess, or dispense legend drugs to dialysis patients, as authorized by the Pharmacy Quality Assurance Commission (Commission). The Commission's rules authorize four products: sterile heparin, sterile potassium chloride, commercially available dialysate, and sterile sodium chloride. In addition, the home dialysis program must have an agreement with a pharmacist to provide any necessary consultation on issues such as the drug distribution process to home dialysis patients and the location used for storage and distribution of the drugs. The Commission also requires that home dialysis programs provide and retain certain records related to shipment and that they maintain a quality assurance program for drug distribution.

Summary of Substitute Bill:

Pharmacy and legend drug regulations may not prevent a manufacturer or wholesaler from selling, delivering, possessing, or dispensing dialysis devices and related legend drugs, including commercially available dialysate, used by home dialysis patients directly to dialysis patients. The requirement that the dialysis devices and drugs be prescribed by a physician or osteopathic physician is expanded to include any practitioner acting within the scope of the practitioner's practice.

Appropriation: None.

Fiscal Note: Available.

Effective Date: The bill takes effect 90 days after adjournment of the session in which the bill is passed.

Staff Summary of Public Testimony:

(In support) This bill is about ensuring that persons undergoing kidney dialysis treatment have the ability to do that in the comfort of their homes. It is more comfortable to have

dialysis at home and it reduces child care costs and transportation costs, especially for those with mobility issues. Home dialysis offers patients the ability to schedule treatments around their personal lives. Home dialysis requires fewer medications due to fewer dialysis treatment cycles.

Current law imposes significant requirements on the distribution of home dialysis supplies and devices by aligning kidney-specific services to those of retail pharmacies. Given the volume of fluid that these products contain, this product is difficult for pharmacies to dispense directly to patients. This bill will help seamlessly deliver home dialysis to Washingtonians by removing unnecessary barriers while maintaining patient safety. This bill will allow manufacturers of dialysis home supplies and devices to be exempted from pharmacy and legend drug laws if they maintain control of the product from manufacturing to the patient. This bill will streamline the operations of dialysis solution and device manufacturers. This policy is aligned with 30 other states.

(Opposed) None.

Persons Testifying: Representative Jessica Bateman, prime sponsor; Leslie Emerick, Fresenius Medical Care North America; Elizabeth Stoll, Baxter Healthcare; and Jenny Arnold, Washington State Pharmacy Association.

Persons Signed In To Testify But Not Testifying: None.