

SENATE BILL REPORT

SHB 1675

As of February 16, 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: Passed House: 1/26/22, 97-0.

Committee Activity: Health & Long Term Care: 2/16/22.

Brief Summary of 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.

SENATE COMMITTEE ON HEALTH & LONG TERM CARE

Staff: Julie Tran (786-7283)

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 such as 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

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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.

The Pharmacy Quality Assurance Commission allows Medicare-approved home dialysis centers or facilities operating Medicare-approved home dialysis programs to sell, deliver, possess, or dispense legend drugs to dialysis patients. There are four authorized products: sterile heparin, sterile potassium chloride, commercially available dialysate, and sterile sodium chloride.

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 Pharmacy Quality Assurance 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 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.

Creates Committee/Commission/Task Force that includes Legislative members: No.

Effective Date: Ninety days after adjournment of session in which bill is passed.

Staff Summary of Public Testimony: PRO: Current law imposes significant requirements on the distribution of home dialysis supplies and devices by aligning kidney-specific services to those of retail pharmacies. This bill will help seamlessly deliver home dialysis to Washingtonians by removing unnecessary barriers while maintaining patient safety. Home dialysis offers many benefits to patients, such as the ability to schedule treatments around their personal lives. This bill will allow manufacturers or wholesalers 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 is similar to many other states and it will streamline the operations of dialysis solution and device manufacturers.

Persons Testifying: PRO: Leslie Emerick, Fresenius Medical Care North America; Jessica Fortescue, Baxter Healthcare; Vince Hanks, Baxter Healthcare.

Persons Signed In To Testify But Not Testifying: No one.