

SENATE BILL REPORT

SB 5507

As of January 18, 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: Senators Keiser, Muzzall, Lovick and Wilson, C..

Brief History:

Committee Activity: Health & Long Term Care: 1/19/22.

Brief Summary of Bill

- Requires that pharmacy and legend drug regulations allow manufacturers of commercially available dialysate and home dialysis equipment to sell, possess, deliver, or dispense dialysis devices and those legend drugs directly to a patient.

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 is a procedure that includes a dialysis machine and a special filter such as a dialyzer, where the blood circulates out of an individual's body and into the special filter machine outside of an individual's body, and once complete, the blood returns back into an

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individual's body. Hemodialysis is usually performed in a health care setting, but may be done at home.

Peritoneal dialysis uses a dialysis solution called dialysate to filter the blood through a catheter into part of the abdomen, which 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.

Home dialysis programs are required to have an agreement with a pharmacist, who can provide any consultation necessary to home dialysis patients. Those consultations are related to the drug distribution process and other issues such as the storage location for the drugs and the drugs' distribution. Home dialysis programs must also maintain a quality assurance program for drug distribution and the programs must provide and retain certain records related to shipment.

Summary of Bill: Pharmacy and legend drug regulations may not prevent a manufacturer of commercially available dialysate and dialysis devices used by home dialysis patients, or a manufacturer's agent, from selling, delivering, possessing, or dispensing dialysis devices and related legend drugs directly to dialysis patients.

Appropriation: None.

Fiscal Note: Requested on January 8, 2022.

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

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