FINAL BILL REPORT SHB 1675

C 23 L 22

Synopsis as Enacted

- **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).

House Committee on Health Care & Wellness Senate Committee on Health & Long Term Care

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 provided in a health care setting, but may be performed 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 dialysis centers and 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. Home dialysis programs 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

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.

quality assurance program for drug distribution.

Summary:

In addition to dialysis centers and home dialysis programs, 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.

Votes on Final Passage:

House	97	0
Senate	48	0

Effective: June 9, 2022