Washington State House of Representatives Office of Program Research

BILL ANALYSIS

Health Care & Wellness Committee

HB 1675

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: Representatives Bateman, Maycumber, Leavitt, Graham, Dolan, Cody, Griffey and Riccelli.

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.

Hearing Date: 1/12/22

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.

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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 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: Available.

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