*Department of Health*
*Pharmacy Quality Assurance Commission*

# Policy Statement

*Revised – 10/18/11*

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| *Title:* | Regulatory Standards Applicable to Manufacturers and Wholesalers of Dialysis Devices and Legend Drugs for Home Dialysis | *Number:* P008 |
| *References:* | Substitute House Bill (SHB) 1675 (Chapter 23, Laws of 2022) codified under RCW 18.64.257 and RCW 69.41.032, WAC 246-945-090, WAC 246-945-091, WAC 246-945-092, and WAC 246-945-093 | |
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| *Effective Date:* | June 9, 2022 | |
| *Supersedes:* | N/A | |
| *Approved By:* | Teri Ferreira, Pharmacy Quality Assurance Commission | |

This policy statement clarifies the regulatory standards applicable to manufacturers and wholesalers of dialysis devices and legend drugs for home dialysis under Substitute House Bill (SHB) 1675 (Chapter 23, Laws of 2022) titled Home Dialysis Patients—Dialysate and Dialysis Devices. Specifically, the Pharmacy Quality Assurance Commission (commission) will expect these manufacturers and wholesalers to operate in a manner that complies with the requirements of SHB 1675 and WAC 246-945-090 through 246-945-093.

In 2022, the Legislature passed SHB 1675 to increase patient access to dialysis devices and legend drugs used in home dialysis. Effective June 9, 2022, manufacturers and wholesalers may sell, deliver, possess, or dispense dialysis devices and legend drugs for home dialysis directly to patients, provided that the treatment was prescribed by a practitioner acting within the scope of their practice. This means, among other things, that manufacturers and wholesalers could sell, dispense, and deliver commercially available dialysate to patients in "case or full shelf lots" for the purpose of reducing intermediary storage facility use (such as warehouses). Prior to SHB 1675 this practice was prohibited.

SHB 1675 grants the commission rulemaking authority to adopt the sections of law amended by the bill to ensure the identified manufacturers and wholesalers are included in sections of the Washington Administrative Code under the commission's jurisdiction pertaining to home dialysis programs. These sections of chapter 246-945 WAC include:

- WAC 246-945-090 Home Dialysis Programs—Legend Drugs,

- WAC 246-945-091 Home Dialysis Program—Pharmacist Consultant,
- WAC 246-945-092 Home Dialysis Program—Records, and
- WAC 246-945-093 Home Dialysis Program—Quality Assurance.

While the commission engages in rulemaking specific to manufacturers and wholesalers of dialysis devices and legend drugs for home dialysis, the commission has determined that:

1. Manufacturers and wholesalers of dialysis devices and legend drugs for home dialysis, and their representatives, must comply with the minimum requirements in SHB 1675. This includes the requirement to be licensed as a manufacturer or wholesaler by the Commission, as appropriate; and
2. Manufacturers and wholesalers of dialysis devices and legend drugs for home dialysis, and their representatives, are expected to comply with WAC 246-945-090 through 246-945-093.

The commission will not take enforcement action against a manufacturer or wholesaler for acting in compliance with the minimum requirements of SHB 1675 and WAC 246-945-090 through 246-945-093. Compliance with all other laws and regulations is required.

For the purposes of this policy statement "legend drugs for home dialysis" includes only: sterile heparin, 1000 u/mL, in vials; sterile potassium chloride, 2 mEq/mL, for injection; commercially available dialysate; and sterile sodium chloride, 0.9%, for injection in containers of not less than 150 mL (*see* WAC 246-945-090).

STATE OF WASHINGTON

DEPARTMENT OF HEALTH

Olympia, Washington

# NOTICE OF ADOPTION OF A POLICY STATEMENT

**Title of Policy Statement:** Regulatory Standards Applicable to Manufacturers and Wholesalers of Dialysis Devices and Legend Drugs for Home Dialysis | P008

**Issuing Entity:** Pharmacy Quality Assurance Commission

**Subject Matter:** This policy clarifies expectations set by the Pharmacy Quality Assurance Commission for manufacturers and wholesalers of commercially-available dialysate and dialysis devices to comply with sections of rule related to existing statutes amended by Substitute House Bill 1675 (Chapter 23, Laws of 2022).

**Effective Date:** June 9, 2022

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