

**Pharmacy Quality Assurance Commission
Memo**

Date: **May 9, 2019**

To: **Robin Bucknell, Health Systems Oversight**
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From: **Steven Saxe, RPh, FACHE**
Executive Director

Subject: **End Stage Renal Disease (ESRD) or Kidney Dialysis Center Authority to Sell, Deliver, or Possess Legend Drugs**
DISCUSSION DRAFT

Question: What are the various avenues an End Stage Renal Dialysis (ESRD) or Kidney Dialysis Center has statutory authority to sell, deliver, or possess legend drugs for the services that they provide?

Answer: The Pharmacy Commission staff have identified the following options for an End Stage Renal Dialysis (ESRD) or Kidney Dialysis Center to sell, deliver, or possess legend drugs.

1. A Medicare-certified kidney dialysis center may sell, deliver, or possess the four legend drugs identified by the Pharmacy Quality Assurance Commission (Commission) in rule ([WAC 246-905-020](#)). A Medicare-certified kidney dialysis center would also need to be in compliance with three other obligations; (i) an agreement with a pharmacist ([WAC 246-905-030](#)), (ii) adequate record keeping ([WAC 246-905-040](#)) and (iii) a quality assurance plan ([WAC 246-905-050](#)).
2. A Medicare-certified kidney dialysis center may sell, deliver, or possess any additional legend drug that are under the control of an authorized practitioner (prescriber) e.g., physician.
3. Additionally, a Medicare-certified kidney dialysis center may sell, deliver, or possess any additional legend drug if they have another appropriate facility license e.g. Health Care Entity (HCE) license. ([RCW 69.41.010](#), [RCW 69.41.030](#) and [RCW 69.50.101](#))

Background: For patient and public safety the sale, delivery, or possession of legend drugs requires legal authorization under state law. Patients may possess drugs following the issuance of a legitimate prescription. Other people or entities may possess legend drugs based on the authority granted under their license. [RCW 69.41.030](#) provides the definition of licensed practitioners and facilities authorized to sell, deliver, or possess a legend drug without a prescription or order prohibited. [RCW 69.41.010\(17\)](#) provides a definition of practitioner to

include “or other institution licensed, registered or otherwise permitted to distribute, dispense...” [RCW 69.50.101](#) provides the definition of licensed practitioners and facilities for controlled substances.

A Medicare-certified kidney dialysis center (dialysis center) does have legal authority to sell, deliver, possess and dispense a limited number of legend drugs under specified conditions. (RCW 18.64.257 and RCW 69.41.032) Currently the rule allows for four drugs, heparin, potassium chloride, dialysate and sodium chloride. ([WAC 246-905-020](#)). The dialysis center must also be in compliance with three other obligations; (i) an agreement with a pharmacist ([WAC 246-905-030](#)), (ii) adequate record keeping ([WAC 246-905-040](#)) and (iii) a quality assurance plan ([WAC 246-905-050](#)).

For a dialysis center to sell, deliver, or possess any additional legend drug, the drug must either be under the control of an authorized practitioner (prescriber) e.g. physician, or they need another appropriate facility license e.g. HCE license with that authority. ([RCW 69.41.010](#), [RCW 69.41.030](#) and [RCW 69.50.101](#))

If a dialysis center elects not to have the drugs under the direct control of a prescriber, they will need an appropriate state license. One option would be an HCE license.

[Health Care Entity License Requirements:](#)

- [Chapter 18.64 RCW](#)
- [Chapter 246-904 WAC](#)

An HCE is an organization that provides health care services in a setting that is not otherwise licensed by the state to acquire or possess legend drugs. An HCE could include facilities such as a residential treatment facility, or a freestanding cardiac care center.

An HCE does not include an individual practitioner's office or a multipractitioner clinic, regardless of ownership, unless the owner elects licensure as an HCE.

An HCE must designate a Washington licensed pharmacist as pharmacist in charge as a full time employee or consultant. The pharmacist in charge shall have the authority and responsibility to assure that the area(s) within the health care entity where drugs are stored, compounded, delivered or dispensed are operated in compliance with all applicable state and federal statutes and regulations.

An HCE license includes the authority to purchase, possess, administer, and dispense controlled substances.

All HCE licensure applicants are inspected before a license is issued and periodically to ensure compliance with laws and rules on purchasing, ordering, storing, compounding, delivering, dispensing and administration of controlled substances and/or legend drugs. Physical requirements for the areas of a health care entity where drugs are stored, compounded, delivered or dispensed shall comply with official United States pharmacopeia standards.

In addition to the options already identified, the kidney dialysis centers or industry could consider a rules petition to add additional drugs to [WAC 246-905-020](#). An option for dialysis centers affiliated with a hospital maybe be to consider becoming a Hospital Pharmacy Affiliated Clinic (HPAC).

Next Steps:

The Pharmacy Commission staff will work with the Office of Community Health Systems and the Office of Health Systems Oversight to schedule a stakeholder meeting with ESRD providers and other interested parties. This will be an opportunity to share the findings above and obtain stakeholder input. The Pharmacy Commission staff will then work with the other offices to develop an interpretive statement to present to the Pharmacy Commission and department for consideration to adopt and publish on options for ESRD providers to sell, deliver or possess.

Cc: Tracy West
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