



## Pharmacy Quality Assurance Commission Guidance Document

<b>Title:</b>	End Stage Renal Disease (ESRD) or Kidney Dialysis Center Authority to Sell, Deliver, or Possess Legend Drugs
<b>Reference:</b>	<a href="#">RCW 69.41.030</a> ; <a href="#">RCW 69.41.010</a> ; <a href="#">RCW 69.50.101</a> ; <a href="#">Chapter 18.64 RCW</a> ; <a href="#">RCW 18.64.257</a> ; <a href="#">RCW 69.41.032</a> ; <a href="#">RCW 18.64.043</a> WAC 249-945-090 thru -093; <a href="#">HPAC FAQ</a>
<b>Contact:</b>	Lauren Lyles-Stolz, PharmD., Executive Director
<b>Effective Date:</b>	August 2, 2019 (reaffirmed/updated August 28, 2020)
<b>Supersedes:</b>	N/A
<b>Purpose:</b>	Identify options for Kidney Dialysis Centers to order, deliver, possess or use legend drugs.
<b>Approved:</b>	Tim Lynch, PharmD, MS, FABC, FASHP, Pharmacy Quality Assurance Commission Chair

**Question:** What is the statutory authority for an End Stage Renal Disease (ESRD) or Kidney Dialysis Center to order, sell, deliver, or possess legend drugs for the services that they provide?

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

1. A Medicare-certified kidney dialysis center operating a Medicare-approved home dialysis program may sell, deliver, or possess the legend drugs identified by the Pharmacy Quality Assurance Commission (Commission) in rule ([RCW 18.64.257](#); [RCW 69.41.032](#); [WAC 246-945-090](#)). A Medicare-certified kidney dialysis center would also need to be in compliance with three other obligations; (i) an agreement with a pharmacist ([WAC 246-945-091](#)), (ii) adequate record keeping ( [WAC 246-945-092](#)) and (iii) a quality assurance plan ([WAC 246-945-093](#)).
2. A kidney dialysis center may sell, deliver, or possess legend drugs that are under the control of an authorized practitioner (prescriber) e.g., physician.
3. A kidney dialysis center may choose to obtain other appropriate facility licensing to order, sell, deliver, or possess legend drug. These might include among others:



- a. A Health Care Entity (HCE) license. ([RCW 69.41.010](#), [RCW 69.41.030](#) and [RCW 69.50.101](#))<sup>1</sup>
- b. If part of a healthcare system with a hospital, a Hospital Pharmacy Affiliated Clinic (HPAC). ([RCW 18.64.043](#); [Chapter 246-945 WAC Part 4](#) ; [HPAC FAQ](#))

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<sup>1</sup> Kidney Dialysis Centers are not required to have an HCE license. Kidney Dialysis Centers were included in the original statutory definition of HCE in 1995. But an amendment in 1997 removed Kidney Dialysis Center in 1997. The Legislative Bill Report provides background on the decision to eliminate the HCE requirement for Kidney Dialysis Centers. The WAC definition of HCE initially developed was not updated to match the 1997 amendment. The Pharmacy Commission has proposed matching the statutory definition of HCE in the current rule rewrite being considered for adoption in 2020.