PUGET SOUND kidney centers
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December 15, 2025

Eric Hernandez, Executive Director
Certificate of Need Program, Washington Department of Health
Via email: eric.hernandez@doh.wa.gov, CNRulemaking@doh.wa.gov

Dear Mr. Hernandez,

PSKC appreciates the Department of Health's (DOH) efforts in developing rules for the CN exemption for in-home kidney dialysis performed in a Skilled Nursing Facility (SNF) and for the opportunity to participate in the November 20, 2025, stakeholder meeting.

While the rules are well-intended to improve access to care, they lack sufficient detail to fully consider possible unintended consequences on patients or to allow the provider community to accurately quantify the impact on existing ESRD center operations.

I. Primary Concerns Regarding Provider Partnerships and Planning Areas

The proposed rule mandating that each SNF partner with only one (1) outpatient ESRD company/clinic located within the same planning area raises significant concerns:

- Undefined Planning Area: The rule does not clearly define which planning area dictates the requirement: the SNF's planning area or the ESRD facility's planning area.

- First Right/Exclusivity Issues: The rule does not address how "first right" will be managed, especially in areas with multiple competing ESRD facilities or in rural areas with no existing ESRD facilities.

- Dissolution of Agreement: There is no clear verbiage or guideline on the process, patient transition, or "first right" if the sole partner company dissolves or terminates the agreement.

II. Patient Transition and Care Continuity

Based on stakeholder discussions, it appears the majority of patients expected to utilize the in-nursing home "home" model will not be current, trained, home dialysis patients. This is concerning given the established model of care:

- Standard Home Training: A typical home dialysis patient undergoes weeks of one-on-one, in-center training with a Registered Nurse and receives extensive ongoing support after transitioning home.

- Unintended Patient/Provider Churn: The requirement for a single partner may force patients to not only change their in-center dialysis provider but potentially their nephrologist—a trusted physician who may have provided care for years.

- Impact on Operations: This patient churn could negatively impact current in-center census levels, existing provider-patient relationships, and billing/reimbursement cycles, as well as CMS reporting measures.

III. Transfer Agreements, Insurance, and Rural Gaps

The current CN rule does address transfer agreements for End-Stage Renal Disease (ESRD) services, while addressing agreement dissolution, however, is critically deficient because it fails to account for the primary factors governing patient placement: insurance coverage and specific payer approvals.

- Functional Viability: This oversight severely limits the practical effectiveness of any proposed transfer agreement, especially in rural planning areas, creating significant "blind spots."

- Risk of Patient Displacement: Should an agreement dissolve and no other ESRD provider exists in the vicinity, patients' risk being left without a provider or being rejected by an alternate SNF—particularly if they are home dialysis patients—potentially leading to patient displacement within Washington or into neighboring states.

IV. Concerns with the Proposed "Den" Model

While the bedside portion of the draft rule is aimed to improve access to care, the proposed "Den Model" needs significant refinement and defining.

- The lack of a limit on the number of stations in a "den" is concerning.

- Care Model Discrepancy: Home dialysis is fundamentally a one-patient-to-one caregiver model. A "den," by definition, implies multiple patients with a single caregiver (or limited number of staff). This fundamentally changes the nature of "home" dialysis care and requires a different staffing/safety framework.

- Modality Specificity: The Den Model is unclear because it does not specify or differentiate between home hemodialysis (HHD) or peritoneal dialysis (PD). Both require specific environmental layouts, distinct equipment, and separate infection control precautions and are two different modalities. The current rule as proposed is improperly lumping these into one "home definition."

PSKC Position: Too many questions remain unanswered for the "den" model to be adopted into rule at this time.

V. Regulatory Oversight and Data Collection

Additional structural concerns include:

- Lack of State Oversight: The discussion that no clear DOH state survey oversight will govern this rule is concerning, as SNFs and ESRD facilities have differing Conditions of Participation (CoPs) governed by the Centers for Medicare & Medicaid Services (CMS). The decision to place policy and staffing entirely on the agreement between the ESRD company and SNF is inadequate without state-level minimum standards.

- Lack of Data Collection: The current proposal includes no requirement for the State to collect or report data on key metrics, which is crucial for evaluation and area planning needs. This data should include:
    - Number of patients served ("saved")
    - Number of treatments provided
    - Quality metrics
    - Number of patients successfully trained for true home dialysis modalities (HHD, PD)

PSKC requests that the Department dedicate more time to evaluating these concerns, emphasizing the significant potential negative impact on smaller rural ESRD centers, rural SNFs, and the critical patient-provider relationship with current nephrologists and ESRD care teams.

Sincerely,

Amanda Crain,
Chief Operating Officer