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September 4, 2025

Eric Hernandez, Acting Executive Director Certificate of Need Program Washington State Department of Health 111 Israel Road SE Tumwater, WA 98501

Subject: FKC South Tacoma - Determination of Reviewability Request

Dear Mr. Hernandez:

Pursuant to Washington Administrative Code 246-310-050, Renal Care Group Northwest, Inc. submits this request for a determination of reviewability regarding a proposed project to offer Transitional Care Unit / Experience the Difference programs at existing CN-approved in-center stations at Fresenius Kidney Care South Tacoma.

A check for the review fee of \$1,925.00, per WAC 246-310-990(1), has been mailed separately.

Please feel free to contact me if there are any questions on this DOR request. I can be reached at <u>John.Rodriguez2@freseniusmedicalcare.com.</u>

Sincerely,

John Rodriguez, BSN, RN

Regional Vice President – Pacific Northwest

Fresenius Medical Care

Determination of Reviewability Request

Fresenius Kidney Care South Tacoma – Transitional Care Unit (TCU) / Experience the Difference (ETD) program

Pursuant to Washington Administrative Code ("WAC") 246-310-050, Renal Care Group Northwest, Inc. ("RCG"), a subsidiary of Fresenius Medical Care Holdings, Inc. ("Fresenius Medical Care"), submits this request for a determination of reviewability ("DOR") regarding a proposed project to utilize existing CN-approved in-center stations at Fresenius Kidney Care South Tacoma ("FKC South Tacoma") to offer Transitional Care Unit / Experience the Difference programs.

Facility Information

- **Entity Name**: Renal Care Group Northwest, Inc., a subsidiary of Fresenius Medical Care Holdings, Inc.
- Facility Name: Fresenius Kidney Care South Tacoma
- Facility Address: 5825 Tacoma Mall Blvd Ste 103 Tacoma, Washington 98409
- CMS Certification number (CCN): 502590
- Planning Area: Pierce 04
- Most Recent CN-Approval / Exemption Activity: CN1757 dated January 4, 2019.
- In-Center Station Count: 24 general in-center and 1 isolation station.

FKC South Tacoma is a CN-approved kidney dialysis facility in the Pierce 04 ESRD Planning Area. It is CMS certified and actively provides in-center services.

Project Description

Across the U.S., some Fresenius Medical Care clinics offer Transitional Care Units ("TCU") and/or Experience the Difference ("ETD") programs. These programs give in-center patients the opportunity to receive in-depth education about various modality options while continuing to receive *in-center hemodialysis*. The following sections provide more details regarding each program offering.

Transitional Care Units

Patients starting dialysis enter a world of unfamiliar technology, terminology, and procedures. During this time, they need support, compassion, and instruction to understand end stage renal disease ("ESRD") and the best ways to manage their own care. To address these needs, Fresenius Medical Care introduced TCU at select dialysis centers nationwide.

In the TCU, patients learn about all their therapy choices and get the resources and confidence to pursue a treatment that best fits their lifestyle — whether home dialysis, in-center hemodialysis, or getting on a transplant waitlist. Because patients are more engaged in their care, they may

achieve better outcomes and see improvements to their health and lifestyle. That means fewer hospital visits, which can help reduce the cost of care and the burden on healthcare systems.¹

What Are Transitional Care Units?

TCUs are designated spaces in dialysis centers meant to give patients encouragement and education as they start dialysis treatments. TCUs typically include four dialysis stations in a specific area of the center. Each station is equipped with the machines, staff, and supplies necessary for a thorough introduction to kidney replacement therapy options —in-center HD ("HD"), home hemodialysis ("HHD"), peritoneal dialysis ("PD"), and kidney transplantation.

Over a three- to five-week period, patients are taught about dialysis, dialysis machines, cannulation, sterilization practices, dietary needs, medications, and more. As part of this personalized approach, clinicians, social workers, and dietitians demonstrate techniques, offer guidance, answer questions, and offer emotional and psychological support. If referred by their kidney doctor, patients can try more frequent hemodialysis for themselves, which provides a therapy experience similar to HHD.

When patients complete the TCU program, they can more confidently decide whether to pursue PD or HHD through home training services or opt to stay with in-center hemodialysis. Of patients who start in the TCU, Fresenius Medical Care has seen between 40 and 50 percent choose a home modality.³

How Are Patients Selected for Transitional Care Units?

While there are no absolute criteria for TCU participation, the primary focus is on people recently diagnosed with ESRD who are new to dialysis. Often, these patients have had little to no modality education and may not be aware of their therapy options. These patients may also be anxious or fearful about starting dialysis and need to feel supported. Others who could benefit from the program include:

- In-center HD patients interested in or ready for home dialysis
- PD patients who need to change modalities due to ineffective therapy
- Patients returning to dialysis after a failed kidney transplant

What Kind of Education Do TCU Participants Receive?

The federal government is encouraging more widespread adoption of home dialysis, and studies point to better patient outcomes with PD and HHD compared to HD.^{4 5} However, many patients

¹ Michael Kraus and Dinesh Chatoth, "Benefits of Home Hemodialysis," Fresenius Medical Care North America, published July 12, 2019, https://fmcna.com/insights/articles/benefits-home-hemodialysis/.

² "Top 5 Reasons Home Dialysis Is Ready to Take Off," Fresenius Medical Care North America, published March 26, 2019, https://fmcna.com/insights/articles/home-dialysis-top-5-reasons/.

³ "A Smoother Start into Dialysis: Q&A with Joe Turk on Transitional Care Units," Fresenius Medical Care North America, published August 19, 2020, https://fmcna.com/insights/articles/joe-turk-transitional-care-units/.

⁴ Michael Kraus and Dinesh Chatoth, "Benefits of Home Hemodialysis," Fresenius Medical Care North America, published July 12, 2019, https://fmcna.com/insights/articles/benefits-home-hemodialysis/.

⁵ "Top 5 Reasons Home Dialysis Is Ready to Take Off," Fresenius Medical Care North America, published March 26, 2019, https://fmcna.com/insights/articles/home-dialysis-top-5-reasons/.

start dialysis with little to no knowledge of their therapy choices.⁶ The goal of a TCU is for participants to learn about treatment options and ESRD care, and complete the TCU program with a clear path forward and the support they need to succeed.

Successful TCU programs require a dedicated, multidisciplinary team and a comprehensive, organized curriculum. TCU teams may include nurses, technicians, dietitians, social workers, financial coordinators, nurse practitioners, physician assistants, and nephrologists. A thorough four-week program may consist of the following: ⁷

Week 1: Patients are welcomed and introduced to their TCU team. The team provides reassurance and stability, helping patients mentally prepare to learn about their dialysis options. They talk with the patient about goals, concerns, and fears. They administer hemodialysis and adjust the patient's prescription and medications as needed.

Week 2: Education begins on the importance of dialysis and desired outcomes. The option of home therapy treatment (PD and HHD) is discussed as well as the option for a transplant. Patients are educated on the importance of their access type and vaccinations. If necessary, hemodialysis prescription and medications are further adjusted.

Week 3: Home therapies are explored further. Participants meet with patients who are already on HHD and PD, hear about the freedom and flexibility as well as the tips for adjusting to therapy, and learn about home dialysis equipment. With permission from their nephrologist, patients can start more frequent hemodialysis and experience the difference in more frequent treatments. The TCU team guides discussions and decisions about next steps and modality choices (PD, HHD, or IHD). Hemodialysis prescriptions and medications may be adjusted once more.

Week 4: When patients feel comfortable with the education provided and have decided their next step, they graduate and begin the transition out of the TCU. In many cases, patients choose home dialysis and only then would begin formal home training services. Plans for vascular access and transplant evaluation appointments are confirmed if relevant, and advanced care planning is discussed.

Overall, the TCU setting provides patients with the information, instruction, and time they need to make confident, informed choices about dialysis modalities and other aspects of care. Most importantly, TCU programs help promote a smooth start to dialysis, care continuity, and better health and well-being for our patients.

⁶ Robert Lockridge Jr., Eric Weinhandl, Michael Kraus, Martin Schreiber, Leslie Spry, Prayus Tailor, Michael Carver, Joel Glickman, and Brent Miller. "A Systematic Approach to Promoting Home Hemodialysis during End Stage Kidney Disease." Kidney360 1, no. 9 (2020): 993-1001. doi: 10.34067/KID.0003132020.

⁷ Robert Lockridge Jr., Eric Weinhandl, Michael Kraus, Martin Schreiber, Leslie Spry, Prayus Tailor, Michael Carver, Joel Glickman, and Brent Miller. "A Systematic Approach to Promoting Home Hemodialysis during End Stage Kidney Disease." Kidney360 1, no. 9 (2020): 993-1001. doi: 10.34067/KID.0003132020.

Experience the Difference

Fresenius Medical Care's ETD program is a similar but distinct program to TCUs. Rather than focusing on patients new to dialysis, ETD offers established in-center hemodialysis patients the opportunity to learn more about other modalities, including home therapy. During this brief 1-2 week trial, the care team guides the patient through more frequent treatment sessions at an incenter station. An ETD trial offers in-center patients the experience to potentially discover some of the benefits made possible by dialyzing more frequently.⁸

By offering this experiential bridge for established in-center patients while TCUs serve those newly entering dialysis, the two programs together expand access to other modalities such as home therapies, and further RCG's goal of improving outcomes and empowering every individual to select the treatment that best fits their life.

DOR Request

FKC South Tacoma is proposing to utilize existing CN-approved in-center stations at Fresenius Kidney Care South Tacoma to offer TCU and ETD programs.

FKC South Tacoma is <u>not</u> seeking to add or remove any in-center stations as part of this request. The TCU/ETD model uses existing in-center stations for both new and established in-center patients to receive in-depth education about modality options and trial dialyzing more frequently. These TCU/ETD patients will remain categorized as in-center, and their treatments will continue to count toward in-center treatment numbers. The primary distinction is that TCU/ETD patients receive more frequent dialysis at the in-center station, offering them the opportunity to experience an alternative therapy option while remaining in-center. After these programs and trials are complete, TCU/ETD patients can then choose to pursue home dialysis through formal home training services or opt to remain in-center.

The proposed TCU and ETD programs will not increase or otherwise change in-center stations at FKC South Tacoma. Further, RCG need not undertake construction or development at FKC South Tacoma to administer the TCU/ETD programs. Therefore, RCG respectfully requests that the Department confirm its proposal to offer TCU and ETD programs at FKC South Tacoma is not subject to CN review.

⁸ Every prescription and treatment schedule are tailored to the individual patient's needs as determined by their physician and care team.