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Via Email

Certificate of Need Program  
Washington State Department of Health  
Attn: Eric Hernandez, Program Manager  
PO Box 47852  
Olympia, WA 98504-7852

**Re: Determination of Reviewability Regarding Kennewick Peritoneal Dialysis Training Program**

Dear Mr. Hernandez:

I am writing on behalf of DaVita Inc. and its subsidiary Total Renal Care, Inc. (collectively, "DaVita") to request a determination of reviewability, pursuant to [WAC 246-310-050](#), that DaVita's planned Kennewick Peritoneal Dialysis Training Program is not subject to CN review.

The Department reviewed a similar request for DaVita's proposed Peritoneal Dialysis Training Program in Tacoma and determined that this facility is not subject to CN Review. The decision, however, specifically states that it is "limited to the facts presented in this determination of reviewability." Although the general facts regarding PD-only facilities, Chapter 70.38 RCW and WAC 246-310 remain, the prior request was specific to a program in Tacoma. Therefore, DaVita is requesting a determination of reviewability for a PD-only training program in Kennewick.

**About DaVita, Inc.**

- DaVita is a leading provider of kidney dialysis for patients suffering from chronic kidney failure, also known as End Stage Renal Disease, or ESRD. DaVita serves more than 200,000 patients across the U.S. and 10 other countries internationally.
- DaVita's mission statement is to "Be the Provider, Partner, and Employer of Choice". Serving patients by providing quality clinical outcomes is paramount. DaVita has instituted a nationally recognized Dialysis Quality Outcomes program and maintains an aggressive Continuous Quality Improvement program.

A peritoneal dialysis training program is fundamentally different from an in-center hemodialysis facility. A detailed comparison table on key differences is appended to this letter for reference.

**Description of Kennewick Peritoneal Dialysis Training Program project**

- The proposed project is a Peritoneal Dialysis Training Program in Kennewick, Washington.
- The Training Program would be built out as a medical office building would, with similar infrastructure needs (e.g. patient exam rooms, nurses' desks, lab area, conference room).
- DaVita would provide patients with PD training and ongoing support visits at this location.
- The Training Program would be surveyed and certified in accordance with Centers for Medicare & Medicaid Services guidelines.

- The Training Program would not be capable of, nor provide in-center hemodialysis services. Should a patient require hemodialysis services, there are existing DaVita in-center hemodialysis units within Benton County for seamless transition of care.

### **Requested Determination of Reviewability**

The Department released a decision regarding a proposed PD training-only program in Tacoma on March 5, 2021, in which it was determined that the PD-only facility proposed is not subject to CN review. The primary reasoning, which is investigated in more detail below, is that a CN may be required for a “health care facility” which includes “kidney disease treatment centers”, and a PD-only facility is not part of the definition of a “kidney disease treatment center.”

The Department may require a CN only for those activities identified in the CN statutes. CN-reviewable activities include “[t]he construction, development, or other establishment of a new health care facility,” [RCW 70.38.105\(4\)\(a\)](#). The definition of a “health care facility” includes “kidney disease treatment centers” per [RCW 70.28.025\(6\)](#) and [WAC 246-310-010](#) (26).

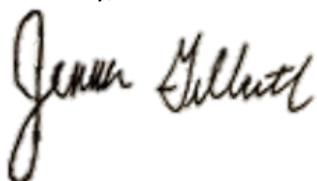
[WAC 246-310-800\(10\)](#) defines “kidney disease treatment center” as “any place, institution, building or agency or a distinct part thereof equipped and operated to provide services, including outpatient dialysis.” PD training-only programs do not fall within this definition as dialysis services in these programs are neither provided nor possible. For PD patients, dialysis occurs at home. It is the training that occurs at the PD training-only programs. To further emphasize the difference, Medicare reimburses separately for “training” services that happen in the training program and the “self-dialysis” that happens at home.

Furthermore, the March 5<sup>th</sup> decision from the Department notes that it does not currently conduct CN review for training accommodations and that they are not considered to be connected with kidney dialysis treatment centers when determining need. The need forecasting methodology for kidney disease treatment facilities in [WAC 246-310-812](#) determines station need for in-center hemodialysis. For example, the statutes determine “the number of dialysis stations projected as needed in a planning area” (246-310-812(4)) and the department criteria for approving “new in-center kidney dialysis stations” in two types of planning areas that are defined based on utilization of in-center kidney dialysis stations (246-310-812(5) and (6)). Stations are not part of PD treatments; instead, PD training rooms are used to train patients to perform their own treatments at home, and for monthly or quarterly visits with their care team. PD training rooms are not included in a facility’s station count and PD patients and the programs which serve them are explicitly removed from the dataset that determine the need build-up.

When reading the CN regulations as a whole, it is clear that the “kidney disease treatment centers” subject to CN review are in-center hemodialysis facilities. These regulations would make no sense in connection with a peritoneal dialysis training program.

If you have any questions about this project, or if the Department needs any additional information to make our requested determination, please do not hesitate to contact me.

Sincerely,



Jenna Gilbreath  
Director – Special Projects

DaVita, Inc.

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	<b>In-Center Hemodialysis Unit</b>	<b>Peritoneal Dialysis Training Program</b>
What is the therapy?	In-center hemodialysis (“ICHD”) is a treatment that filters the blood of wastes and extra fluid when the kidneys are no longer able to perform this function	Peritoneal dialysis (“PD”) is a needle-free treatment using the lining of the abdomen to filter waste from the blood
Where is it performed?	At a designated dialysis station in a dialysis unit	At home, either during the day or at night while sleeping
Who performs the treatments?	Trained renal professionals, including patient care technicians and renal nurses	The patients themselves, following an eight-day training period
At what typical frequency do the treatments occur, and where?	Three times per week, for 4 hours per treatment, at the dialysis unit	Daily, at the patient’s home
How often does the patient come to the physical unit/ program?	Three times per week, and sometimes more frequently, when health dictates need for additional treatments to stay healthy	In order to be successful performing PD in their homes, patients are trained during eight appointments over approximately two weeks by a PD nurse in a home training program room.  After a patient is trained, patients visit the program once per quarter to meet in-person with their nephrologist, if the patient opts for telehealth and completes lab draws elsewhere. Alternatively, the patient visits 1-2 times per month. The patient generally meets with the interdisciplinary team and completes lab work during those visits.
How are patient outcomes on the therapy?	Studies have found no significant overall difference in mortality risk in hemodialysis patients compared to peritoneal dialysis patients.	Studies have found improvement in outcomes in PD patients in multiple subgroups, as PD better preserves remaining kidney function than hemodialysis. The continued ability to make urine leads to enhanced clinical outcomes. There are shorter recovery times between treatments, as PD's daily treatments more closely mimic the kidney's natural function.
What equipment requirements exist?	At a designated dialysis station, patients are connected to a dialysis machine, for filtration and ongoing monitoring throughout treatment. Ultra filtered water is needed to perform dialysis, so each facility must have a water treatment room with equipment such as a reverse osmosis machine, chlorine tanks, in addition to a large number of	Patients on daytime PD may use gravity and an IV pole or a small cyclor in their home to facilitate the filling and draining of the stomach lining to filter waste.  Patients on nighttime PD use a small cyclor device to automate the filling and draining of the stomach lining.

	<p>treatment supplies, such as dialyzers.</p>	<p>PD training rooms require two sinks and a room with a chair, similar to a primary care physician's space.</p> <p>PD programs do not have stations consisting of dialysis machines that are connected to a centralized water system.</p>
<p>What is the role of water in patient treatment?</p>	<p>ICHD treatment requires needles to route water and fluid through the machine to clean the blood.</p> <p>The water must be ultra-pure and safe as it enters the body, requiring use of a water room in each clinic.</p> <p>Water systems are a point of failure that could take down the treatment capabilities of an entire treatment facility or make an entire group of patients very sick if the water isn't treated appropriately. Water systems testing is a key part of state dialysis surveys for safety.</p> <p>Each unit's water room is very expensive to build and maintain. The need for a water room limits the real estate possibilities and location of a clinic, as each clinic needs a reliable water source. It is generally a bad idea to locate water rooms on 2nd floors or higher, because they can leak and cause a lot of damage.</p>	<p>Water does not play a role in a PD treatment. PD uses no needles. For the treatment, a specialized fluid is placed into the patient's peritoneal cavity through an abdominal catheter. The treatment then uses the patient's internal membrane to filter toxins, which preserves kidney function for longer.</p> <p>There is no single point of treatment failure in a PD program as only patient training and clinic visits are provided at the program. Treatments are self-provided in patients' homes. The patients do not need to have a reliable water source as the fluid for PD is shipped to patients in pre-packaged bags by a national supplier.</p> <p>Given the lack of water room and its associated real estate requirements, it is much easier to find appropriate real estate for PD programs. For example, they can be located on any floor of a building.</p> <p>PD is socially distanced by its nature as each patient performs their own treatments at home. Office visits with a patient's nephrologist and nurse can often be handled via telehealth.</p>