

January 26, 2023

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 Home Hemodialysis 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 <u>WAC 246-310-050</u>, that DaVita's planned Kennewick Home Hemodialysis ("HHD") Training Program is not subject to CN review.

The proposed HHD Training Program is consistent with the programs approved under DOR 22-11, DOR 21-36 and DOR 21-35 and will take place at the same location that was approved to provide Peritoneal Dialysis Training under DOR 21-30.

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.

Description of Kennewick Home Hemodialysis Training Program project

• The proposed project is a Home Hemodialysis Training Program in Kennewick, Washington at the following address:

6816 West Rio Grande Ave. Suite B Kennewick, WA 99336

- The proposed program will operate largely the same as the facilities approved under DOR 21-02, 21-30, 21-31, and 21-32 in that DaVita will provide home training services. The only difference is the type of home dialysis being proposed.
- 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) as shown in the single-line drawing included in Exhibit A.
- DaVita would provide patients with HHD 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 in-center hemodialysis services, there are existing DaVita in-center hemodialysis clinics within Benton and Franklin County for seamless transition of care.

Requested Determination of Reviewability

The Department released a decision regarding two proposed HHD training programs in Yakima and Whatcom (DOR 21-35 and DOR 21-36) on September 17, 2021 and an additional HHD training program in Yakima (DOR 22-11) on December 23, 2021, in which it was determined that the HHD 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 an HHD 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." HHD training-only programs do not fall within this definition as dialysis services in these programs are neither provided nor possible. For HHD patients, dialysis occurs at home. It is the training that occurs at the HHD training 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, in the decisions referenced above 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 <u>WAC 246-310-812</u> determines <u>station need for in-center hemodialysis</u>. 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 HHD treatments; instead, HHD training rooms are used to train patients to perform their own treatments at home, and for monthly or quarterly visits with their care team. HHD training rooms are not included in a facility's station count and HHD 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 home hemodialysis 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.

Jenna.gilbreath@davita.com

(724) 462-7102

Exhibit A Single Line Drawing

1 PD #3
148 SF

PD #2 148 SF

148 SF

ALTERNATE TRAINING

ROOM LAYOUT



D.O.C.

D.M.:

P.M.: R.O.D.:

BIOMED: C.S.S.:

S.O.S./S.A.I.L

+ F.A.: + PD-HHD P.M.:

+ = IF APPLICABLE

DAVITA_KENNEWICK_PD 6917_GRANDRIDGE SUITE_BZ KENNEWICK_WA

KRISTIN_VIDETO DREAM_TEAM

HOPE

PFP-6