



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504

September 17, 2021

Jenna Gilbreath, Director – Special Projects
DaVita, Inc.
32275 – 32nd Avenue South
Federal Way, Washington 98001
e-mail: Jenna.Gilbreath@davita.com

RE: Determination of Reviewability #21-30 Kennewick PD Facility

Dear Ms. Gilbreath:

The Department of Health (Department) has completed the review of your request regarding the establishment of a peritoneal dialysis training program facility that does not provide any in-facility dialysis services in Kennewick, Washington. This determination of reviewability request asks whether a facility exclusively dedicated to training services for peritoneal dialysis patients is a “health care facility” under RCW 70.38.025(6) and WAC 246-310-010(26). Throughout this evaluation, such facilities will be referred to as “PD-only facility.”

Below is the information considered and the facts relied upon by the Certificate of Need (CN) Program in reaching its conclusion regarding your request.

SOURCE INFORMATION CONSIDERED

- DaVita’s reviewability request.
- DaVita’s screening response and supplemental information.
- Public comment submitted on behalf of Nonprofit Dialysis Providers [Northwest Kidney Centers, Olympic Peninsula Kidney Centers, and Puget Sound Kidney Centers, collectively].
- Public comment submitted on behalf of Fresenius Medical Care North America.
- DaVita’s rebuttal comments
- Certificate of Need Program’s evaluation of Determination of Reviewability #21-02
- Revised Code of Washington (RCW) 70.38.
- Washington Administrative Code (WAC) 246-310.
- 42 Code of Federal Regulations (CFR) Title 42, Chapter IV, Subchapter G, Subsection 494
- 2005 CN rules
- 2006 ESRD rulemaking records
- 2016 ESRD rulemaking records

PUBLIC COMMENT AND RESPONSE

Following submission of this determination of reviewability request, the Department received comments from Northwest Kidney Centers, Puget Sound Kidney Centers, and Olympic Peninsula Kidney Center acting collectively under the name “Nonprofit Dialysis Providers.” Additionally, comments were also received from Fresenius Medical Care North America. When the CN Program receives comments regarding determinations of reviewability, all relevant comments are considered. DaVita was given the opportunity to respond to the Nonprofit Providers’ concerns in response to screening. The Nonprofit Providers’ comments, DaVita’s response to these comments, and Fresenius Medical Care North America’s comments were considered in this review.

DEPARTMENT ANALYSIS

Current Statutes and Rules

RCW 70.38.105(3) prohibits persons from engaging in “*any undertaking which is subject to certificate of need review under [RCW 70.38.105(4)] without first having a received from the department either a certificate of need or an exception granted in accordance with this chapter.*” RCW 70.38.105(4)(a) makes the construction, development, or establishment of a new “*health care facility*” subject to CN review. Based on this directive, applicability of the chapter to PD-only facilities is dependent on whether a proposal concerns a facility that meets the definition of “health care facility.”

RCW 70.38.025(6) defines a “health care facility” to mean: “*hospices, hospice care centers, hospitals, psychiatric hospitals, nursing homes, **kidney disease treatment centers**, ambulatory surgical facilities, and home health agencies....*” [**emphasis added**] WAC 246-310-010(26) defines a “health care facility” in the pertinent part as follows: “*Health care facility*” means *hospitals, psychiatric hospitals, nursing homes, **kidney disease treatment centers including freestanding dialysis units**, ambulatory surgical facilities, continuing care retirement communities, hospices and home health agencies,...*” [**emphasis added**] Therefore, a PD-only facility providing training services for peritoneal dialysis patients would be subject to CN review if it falls within the definition of “kidney disease treatment center.”

Dialysis services are specifically governed under CN rules WAC 246-310-800 through WAC 246-310-830. The definition of “Kidney Disease Treatment Center” under WAC 246-310-800(10) is: “*Kidney disease treatment center*” or “*kidney dialysis facility*” means *any place, institution, building or agency or a distinct part thereof equipped and operated to provide services, including outpatient dialysis. **In no case will all stations at a given kidney disease treatment center or kidney dialysis facility be designated as self-dialysis training stations.** For purposes of these rules, kidney disease treatment center and kidney dialysis facility have the same meaning.*” [**emphasis added**]

WAC 246-310-812, which addresses need forecasting methodology, opens with the following statement: “*A kidney dialysis facility that provides hemodialysis or **peritoneal dialysis, training, or backup** **must** meet the following standards in addition to applicable review criteria in WAC [246-310-210](#), [246-310-220](#), [246-310-230](#), and [246-310-240](#).*” [**emphasis added**]

WAC 246-310-800(21) defines “training services:”

"Training services" means services provided by a kidney dialysis facility to train patients for home dialysis. Home training spaces are not used to provide in-center dialysis treatments. Spaces used for training are not included in the facility's station count for projecting future station need or in calculating existing station use. Stations previously designated as "training stations" may be used as in-center dialysis stations and will continue to be included in the facility's current station count for projecting future station need or in calculating existing station use. For the purpose of awarding the point for home training in the superiority criteria section (WAC [246-310-823](#)), training services include the following:

- (a) Home peritoneal dialysis (HPD); and*
- (b) Home hemodialysis (HHD).*

WAC 246-310-827, which establishes points-based superiority criteria to compare competing applications, awards points for providing training services.

Prior Versions of the Rules

The program also examined the recent rulemaking history of the kidney dialysis CN rules. Except for the period between 1993 and 2007, it does not appear that the Department considered training facilities in connection with kidney dialysis treatment centers when calculating need. Between 1993 and 2007, the methodology used to calculate need for dialysis stations included a determination of the number of stations needed for home hemo and peritoneal training. See WAC 246-310-280 (2005). However, the methodology that became effective in 2007 no longer counted training beds, but instead provided tiebreaker points to a facility that provided training services. See WAC 246-310-284, 288 (2007).

The 2006 rule-making file included a Concise Explanatory Statement (copy attached) which provides background to explain the meaning of the second sentence in the current WAC 246-310-800(10) about not designating all stations as self-dialysis training stations. The proposed 2006 rule defined kidney dialysis treatment centers under WAC 246-310-280(6) the same as the current definition. The Department received a public comment asking the second sentence to be dropped. The Department’s response was that the Department “did not eliminate the second sentence. The intent of the committee was that dialysis facilities not be solely for the purpose of self dialysis training.” See page 34 of the attached concise statement.

Discussion

- The applicable statute does not define “kidney disease treatment facility.”
- The Department has been delegated the authority to define the term.
- The Department’s definition for kidney disease treatment centers is ambiguous as to whether it includes training facilities that do not provide in-center dialysis
- The Department does not currently conduct CN review for training space, rooms, or equipment (“training accommodations”), there is no methodology to determine the need of the population to be served, and a kidney dialysis treatment center does not include training accommodations in the facility’s station count.

- The second sentence in WAC 246-310-800(10) – “*In no case will all stations at a given kidney disease treatment center or kidney dialysis facility be designated as self-dialysis training stations*” – lacks clarity. DaVita asserts the meaning of the second sentence is that a facility exclusively dedicated to home training services does not meet the definition of a kidney disease treatment center. The Nonprofit Providers assert the second sentence of this definition must be interpreted as meaning a facility exclusively dedicated to home training services is not permitted. We believe the Nonprofit Providers’ interpretation is invalid because it assumes the Department’s CN Program has the authority to prohibit the establishment of a health care facility. The CN program does not have authority to prohibit a type of facility. If a facility is subject to CN review, the Department must conduct review and either approve or deny the application.
- It is clear that since 2007, the Department has not considered dialysis training accommodations to be subject to CN review. At present, the Department does not have enough information to conclude that CN review of such accommodations serves the purposes for which the Legislature established the CN program.
- DaVita confirms this location will not be capable of providing in-center hemodialysis services.
- Because training accommodations in general are not subject to CN review, the PD-only facility proposed by DaVita is not subject to CN review under the current rules.
- If new information is made available to or discovered by the Department demonstrating that PD-only facilities like the one proposed by DaVita should be subject to CN review, the Department may undertake rulemaking to change the definition of “kidney disease treatment center,” WAC 246-310-800(10), to include PD-only facilities and establish review standards to determine the criteria for such facilities.

CONCLUSION

In conclusion, based on the totality of information considered, including a review of Chapter 70.38 RCW and WAC 246-310, the PD-only facility proposed by DaVita is not included under the definition of “kidney disease treatment center” and is therefore not subject to CN review. This decision is limited to the facts presented in this determination of reviewability.

The above analysis is applicable under the current kidney dialysis rules. The CN Program has filed a CR-101 on the entire chapter of CN rules. Our stakeholder workshops will afford the stakeholder community the opportunity to discuss CN broadly and the concept of a home-training dialysis facility more specifically. We look forward to your participation as a part of this dynamic discussion.

APPEAL OPTION

This decision may be appealed. You or any person with standing may request an adjudicative proceeding to contest this decision within 28 calendar days from the date of this letter. The notice of appeal must be filed according to the provisions of Revised Code of Washington 34.05 and Washington Administrative Code 246-310-610. A request for an adjudicative proceeding must be received within the 28 days at one of the addresses listed on the following page.

Mailing Address:

Physical Address

Jenna Gilbreath, DaVita, Inc.
DOR #21-30
September 17, 2021
Page 5 of 5

Department of Health
Adjudicative Service Unit
Mail Stop 47879
Olympia, WA 98504-7879

Department of Health
Adjudicative Service Unit
111 Israel Road SE
Tumwater, WA 98501

If you have any questions or would like to arrange for a meeting to discuss this decision, please call me at (360) 236-2955.

Sincerely,

A handwritten signature in black ink, appearing to read "Eric Hernandez", with a long horizontal flourish extending to the right.

Eric Hernandez, Program Manager
Certificate of Need
Community Health Systems

cc: Department of Health, Office of Health Systems Oversight