



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504

August 31, 2023

Charles Minn, MD, Senior VP & Clinical Specialty Services
Pacific Medical Dialysis Services, LLC
E-mail: charles@pacmsg.com

Teresa Andree, Administrator
Park Rose Care Center

RE: Determination of Reviewability #23-16

Dear Dr. Minn and Ms. Andree:

The Department of Health (Department) has completed the review of your joint determination of reviewability request regarding the establishment of standalone home hemodialysis services at the skilled nursing facility known as Park Rose Care Center (Park Rose). According to information provided in the determination of reviewability request and subsequent screening responses, Pacific Medical Dialysis Services, LLC (Pacific Medical) proposes to provide dialysis services within space at Park Rose located at 3919 South 19th Street, Tacoma [98405], in Pierce County. This request asks whether the provision of home hemodialysis support by skilled nursing staff and the external management of training and support for these services establishes a “health care facility” under RCW 70.38.025(6) and WAC 246-310-010(26).

After reviewing all information provided by the joint applicants, the Department concludes that the project as presented is not reviewable as the establishment of a “health care facility” under RCW 70.38.025(6) and WAC 246-310-010(26). As a result, no additional Certificate of Need review or approval is required before Pacific Medical can provide training services within space at Park Rose.

Below is the information considered and the facts relied upon by the Certificate of Need (CN) Program in reaching its conclusion regarding your request.¹

SOURCE INFORMATION CONSIDERED

- Park Rose and Pacific Medical’s reviewability request received March 15, 2023.

¹ The application requests an expedited review of this determination of reviewability under WAC 246-310-150. Expedited reviews are limited to full Certificate of Need applications. Given that your application is a Determination of Reviewability, the expedited review process is not an option for review of this project.

- Park Rose and Pacific Medical’s first and second screening responses and supplemental information received on April 20, 2023, and July 28, 2023, respectively.
- Signed addendum to Medical Director Agreement received on June 27, 2023.
- Revised Code of Washington (RCW) 70.38.
- Washington Administrative Code (WAC) 246-310.
- Pacific Medical Specialty Group’s website at <https://www.pacmsg.com>
- Park Rose’s website at <https://www.regency-pacific.com/senior-living/wa/tacoma/park-rose-care-center>
- 42 Code of Federal Regulations (CFR) Title 42, Chapter IV, Subchapter G, Subsection 494
- Centers for Medicare & Medicaid Services (CMS) Survey Process for Reviewing Home Dialysis Services in a Long Term (LTC) Facility [Ref: QSO-18-24-ESRD]
- CMS Revisions to the State Operations Manual (SOM), Chapter 2, ESRD Program [QSO-18-22-ESRD]
- Comment provided by the Department of Health’s Office of Health Systems Oversight (OHSO)
- Department’s Determination of Reviewability (DOR) #21-02 Tacoma PD Facility Evaluation

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.*” The following statutes describe undertakings requiring review, and are potentially applicable to the establishment of Skilled Nursing Facility-Home Hemodialysis (SNF-HHD) services:

1. The Proposal Is Not Subject to CN Review as a Nursing Home Expenditure

RCW 70.38.105(4)(g) makes “*the construction, renovation, or alteration of a nursing home or change in nursing home services in excess of the expenditure minimum made in preparation for any undertaking under this subsection,*” subject to CN review. As of the time of this determination, the current capital expenditure minimum dollar threshold established by the CN Program is \$2,834,165.

The submitted determination request states there will be no build out costs in implementing a new SNF-HHD service within Park Rose. This is a reasonable assumption based on the proposed bedside delivery of dialysis. Based on this information, the proposed SNF-HHD service would not exceed the current capital expenditure minimum, and review would not be required under RCW 70.38.105(4)(g).

2. The Proposal Is Not Subject to CN Review as a New Kidney Disease Treatment Center

Current Statutes and Rules

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 SNF-HHD facilities is dependent on whether a proposal concerns the establishment of 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 facility providing home hemodialysis services within a skilled nursing facility would be subject to CN review if it falls within the definition of “kidney disease treatment center.”

Dialysis facilities 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.*”

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).*

The CMS Revisions to the SOM, Chapter 2, ESRD Program – 2271A offers the following breakdown of options for residents of nursing homes receiving chronic dialysis treatments:

1. *In-Center Dialysis:*

- *Transporting the resident to and from a separately certified ESRD facility that is located off-site of the nursing home for dialysis treatments; or*
- *Transporting the resident to and from a separately certified ESRD facility providing in-center dialysis located within the nursing home or proximate to the nursing home building.*

2. *Home Dialysis in a Nursing Home:*

Residents may receive dialysis treatments in the nursing home. These dialysis treatments are administered and supervised by personnel who meet the criteria for training, and competency verification in 42 CFR 494.100(a) and (b) as also stated in this guidance, and are provided through a written agreement between the nursing home and the ESRD facility.

Discussion

- The applicable statute does not define “kidney disease treatment facility.”
- The Department has been delegated the authority to define the term.
- The Department does not currently conduct CN review for home dialysis services and currently has no methodology to determine the need of the population to be served by such services. When evaluating the proposed expansion of, or establishment of a new kidney disease treatment center, the Department does not consider the number of home dialysis patients, either as peritoneal dialysis (HPD) or home hemodialysis (HHD).
- Within the application, Pacific Medical described the proposed delivery of services as follows:
“To carry out our proposal, we will work with the SNF/NF to train and educate the employee designated and hired by the SNF/NF to perform dialysis duties. The training and education will be provided by the staff of Pac MSG on how to perform individual dialysis on SNF/NF patients. For each individual SNF/NF patient, they will have individualized home hemodialysis education by our dialysis education staff/Nurse (Pac MSG). We will monitor their techniques and analyze their troubleshooting of dialysis related problems so that they can independently run dialysis for these patients 3-4/week pending prescription. Staff of Pac MSG will continue with our monthly visits with each patient and his/her caregiver/dialysis performer and will be available for any questions if any issues arise...”

We are planning to provide home training to patients and their care partners at our office in 3919 S 19th St, Tacoma, WA 98405, to help the family member/care-taker to be fully trained for home hemodialysis, if they desire. After this training and transition takes place, they will follow up with their respective outpatient nephrologist...

In each SNF/NF, dialysis machines will be brought to each SNF/NF, and the SNF/NF staff will perform the dialysis.”

Pacific Medical further elaborated within screening responses, *“The dialysis FA (facility administrator)/manager, and dialysis nurse(s) will be employed by Pacific Medical Dialysis Services, LLC who will educate, trouble-shoot, and oversee the individual who administers dialysis. These individuals performing dialysis on the residents in the SNF/NF will be employed by the facility, NOT by Pacific Medical Dialysis, but we will work closely with them to make sure appropriate training and education is given.”*

- Under the proposal, Pacific Medical would be providing administrative and staff training services, with occasional home training to patients, and Park Rose residents would receive HHD directly from SNF/NF staff acting as caregivers.
- The Department of Health’s Office of Health Systems Oversight (OHSO) affirmed to the CN program on a separate but related DOR request, that services not directly involving teaching patients to perform dialysis themselves, or services administered by outside staff, would constitute a separately certified dialysis service. [See Exhibit A.]
- Because training accommodations in general are not subject to CN review, the services proposed by Pacific Medical and Park Rose are not subject to CN review under the current rules.

CONCLUSION

In conclusion, based on the totality of information considered, including a review of applicable statutes, rules, and CMS guidance, and in consultation with OHSO, the services proposed by Pacific Medical and Park Rose are not included under the definition of a “kidney disease treatment center” and are therefore not subject to CN review. This decision is limited to the facts presented in this determination of reviewability.

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

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

Charles Minn, Pacific Medical Dialysis Services, LLC
Teresa Andree, Park Rose Care Center
DOR #23-16
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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", written over a light blue horizontal line.

Eric Hernandez, Program Manager
Certificate of Need
Community Health Systems

Attachment

cc: Department of Health, Office of Health Systems Oversight
Department of Social and Health Services, Office of Residential Care Services

Exhibit A

Struska, Andrew (DOH)

From: Rinedahl, Jeux A (DOH)
Sent: Wednesday, July 6, 2022 11:42 AM
To: Struska, Andrew (DOH)
Subject: RE: Discovery Nursing & Rehabilitation of Vancouver Home Dialysis

Hello Andrew,

I don't have anything new, however my interpretation of the process we were informed about was going to end up being DOH domain. The reason for this is that nursing homes are short-term rehab facilities. There is a concern of how the patient gets to DaVita (if not one of their own) and then how the handoff occurs at discharge.

The scenario that was shared with us was that DaVita staff are doing all the work, without the intention of ever teaching the patient to perform the dialysis on their own, as is the standard with home therapy. If a 'resident' is physically moved from their room/bed to a specific dialysis location where outside staff (DaVita) are performing the service, and then the patient is transported back to their room.

Because of the physical movement to a specifically designed dialysis room/unit which has no other purpose or function than this dialysis unit, the outside staff are performing the dialysis treatment, and the intention is not to have any patient involvement in their care or treatment, this is an in-center dialysis unit located in a NH. For these reasons, we would consider this in our domain, and my survey team would be the ones to do an initial and recertification surveys.

Where it will get tricky is investigating complaints. There is a crossover of DOH and DSHS so a complaint might take coordination with two different entities, or one of the departments taking over the entire investigation.

I hope this helps,
Alexander

J. Alexander Rinedahl, RN, MSN

Pronouns: He/His/Him

Outpatient Clinical Care Facilities Manager

Inspections and Investigations

Office of Health Systems Oversight

Washington State Department of Health

Alexander.rinedahl@doh.wa.gov

360-236-2921 | www.doh.wa.gov



From: Struska, Andrew (DOH) <Andrew.Struska@doh.wa.gov>
Sent: Tuesday, July 5, 2022 12:09 PM
To: Rinedahl, Jeux A (DOH) <Alexander.Rinedahl@doh.wa.gov>
Subject: Discovery Nursing & Rehabilitation of Vancouver Home Dialysis

Hello Alexander,

I hope you had a good weekend. I wanted to follow up on the discussion from last month regarding ESRD in nursing homes.

I'm moving through DaVita and Prestige's request to CN regarding home hemodialysis within their Vancouver facility and wanted to see if you had received a response from CMS on the subject. Additionally, I wanted to see if there was any other new information related to home hemodialysis in nursing homes you may have, or any general impressions or interpretations as a subject matter expert that would help in determining if this is a dialysis center for CN purposes.

Thank you very much for your time, and if you have any questions for me please do not hesitate to ask.

Best,
Andrew

Andrew Struska

Management Analyst
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