



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504

October 14, 2022

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

Stacy Mesaros, Administrator
Burien Post Acute Services, LLC

RE: Determination of Reviewability #22-27

Dear Dr. Minn and Ms. Mesaros:

The Department of Health (Department) has completed the review of your joint request regarding the addition of dialysis services at the skilled nursing facility known as Burien Nursing and Rehabilitation (Burien Nursing). 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 Burien Nursing located at 1031 Southwest 130th Street, Burien [98146], in King County.

After reviewing all information provided by the joint applicants, the Department concludes that the project as presented is the establishment of a “health care facility” under RCW 70.38.025(6) and WAC 246-310-010(26). As a result, prior Certificate of Need review and approval is required before Pacific Medical can provide the dialysis services within space at Burien Nursing.

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

- Burien Nursing and Pacific Medical’s reviewability request received September 15, 2022.
- Burien Nursing and Pacific Medical’s first and second screening responses and supplemental information received on July 8, 2022, and August 28, 2022, respectively.
- Revised Code of Washington (RCW) 70.38.
- Washington Administrative Code (WAC) 246-310.
- Pacific Medical Specialty Group website at <https://www.pacmsg.com>
- Burien Nursing’s website at <https://www.burienrehab.com>
- 42 Code of Federal Regulations (CFR) Title 42, Chapter IV, Subchapter G, Subsection 494

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.

- 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) centers:

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 Burien Nursing. 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 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).

- The Department affirmed in DOR #21-02 that it does not conduct CN review for facilities providing only training services for HPD. The decision reached in DOR #21-02 does not apply to this DOR because, as stated by the applicants, the patients would not receive HPD or HHD training while in the nursing home. Any patient discharged from nursing home would have the option of seeking HPD or HHD training at an in-center hemodialysis (ICHD) center. As a result, the dialysis services proposed to be provided at Burien Nursing are not HPD or HHD training.
- Under the proposal, Pacific Medical would be providing dialysis services and would admit patients for its services as HHD patients.
- Under the proposal, Pacific Medical's nurses and technicians would administer dialysis treatment to patients via hemodialysis stations using Tablo dialysis machines. In the event of a patient transferring out from Burien Nursing, Pacific Medical would discharge the patient from the SNF-HHD program and patients will continue receiving dialysis care at an outpatient center.
- In the screening responses, Pacific Medical indicated, *"Once the patient is ready to be discharged, we will then work with the outpatient dialysis center to transition them back to their outpatient units. We will also identify individuals who are interested or have family member interested in home hemodialysis, and will work with outpatient dialysis units and outpatient nephrologist to get them entered into these programs as soon as possible."*

Pacific Medical further elaborated in additional responses, *"We are planning to identify the individuals who have the capability, as well as a family support system, that would be able to continue with home hemodialysis. Once we identify these patients, our goal is to plan for providing education, and also for referral so they are able to continue with home hemodialysis upon discharge. We are planning to create a program for this where we will work in conjunction with their outpatient nephrologist and outpatient dialysis center."*

- 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 would constitute a separately certified dialysis service. [See Exhibit A.]
- Because the joint proposal submitted by Burien Nursing and Pacific Medical proposes to provide dialysis services that are not exclusively HPD or HHD training services, this project meets the definition under WAC 246-310-800(10) as a kidney disease treatment center subject to CN review under RCW 70.38.105(4)(a) and (h). The fact that it is a separately CMS certified in-center facility supports this conclusion.

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 facility proposed by Pacific Medical and Burien Nursing would qualify under the definition of a "kidney disease treatment center" and is therefore subject to CN review. This decision is limited to the facts presented in this determination of reviewability.

Charles Minn, Pacific Medical Dialysis Services, LLC
Stacy Mesaros, Burien Post Acute Services, LLC
DOR #22-27
October 14, 2022
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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

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,



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

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