

**RECEIVED**

By Andrew Struska at 11:04 am, Dec 20, 2023

December 5, 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 Avalon Care Center - Federal Way Home Hemodialysis Skilled Nursing Facility ("SNF") Dialysis Program**

Dear Mr. Hernandez:

We are writing on behalf of DaVita Inc. and its subsidiary Total Renal Care, Inc. (collectively, "DaVita") and Avalon Health Care Group to request a determination of reviewability, pursuant to WAC [246-310-050], that our planned joint program for Home Hemodialysis at Avalon Care Center - Federal Way (a Skilled Nursing Facility or "SNF") is not subject to Certificate of Need ("CN") review.

We acknowledge that the Department reviewed a similar request for DaVita's proposed SNF Dialysis Program with Avalon Care Center – Federal Way on August 2, 2022 and determined that that such a project is subject to a CN review. However, since then, CMS has issued QSO-18-24-ESRD, reaffirming that this model is categorized as Home Hemodialysis (HHD), typically not subject to CN review in the state of Washington. Additionally, Washington recently granted an exception in DOR23-16, which is similar to our project in that our proposed HHD program will not provide in-center dialysis, rather it will provide home hemodialysis services to residents within the SNF/NF that would contract DaVita's services. **In light of this additional CMS guidance and the supporting analysis below, we believe that this proposed model of on-site SNF dialysis supports CN goals and conforms with applicable rules and regulations. We ask that the Department provide fresh consideration to this submission and determine that the proposed program is not subject to CN review.**

The Certificate of Need program is intended to effectuate the goals of Washington's statewide health resources strategy: providing accessible health services, health facilities, and other resources while controlling increases in costs. We believe that on-site dialysis services at SNFs, such as those provided by DaVita at 80 locations in 20 states, contribute meaningfully to these goals and should not be subject to additional CN review. The key reasons we believe this to be the case are:

- a) CMS clearly considers SNF dialysis to be home hemodialysis ("HHD"), and the previous determination of reviewability was erroneous in stating that the program would be associated with an in-center facility (per CMS requirements, each DaVita SNF Dialysis program is associated with a certified HHD program). The CN department "does not currently conduct CN review for home dialysis services." (EvalDOR23-03)
- b) The Department's primary argument against regulating den-based SNF dialysis programs as HHD is that the den should instead be considered a kidney disease treatment facility ("KDTF") and subject to corresponding rules and regulations. In this regard, KDTF is insufficiently defined in WAC: "any place...equipped and operated to provide services" could apply to an in-center facility, an HHD patient's home dialysis space, a SNF resident's room, or a SNF treatment den.

- c) When WAC language was originally drafted, a den-based model was not contemplated, as CMS had not yet issued detailed guidance, there were no such programs in Washington, and there were few such programs elsewhere.
- d) Clinical evidence demonstrates that den-based, on-site dialysis for SNF residents provides improved outcomes compared to patients who are transported to a kidney disease treatment facility (“KDTF”), **including a 15% reduction in hospital readmissions** (*DaVita internal outcomes analysis, 2023*)
- e) On-site dialysis also improves the patient experience and saves SNFs, Medicaid/Medicare, and third-party payors substantial expense by eliminating the cost of transportation to and from KDTFs three or more times per week per patient (often by ambulance).
- f) On-site dialysis programs will not compete with a KDTF or conflict with the patients per station requirements included in WAC 246-310-812, because SNF patients requiring dialysis ultimately discharge from the SNF and return to or initiate treatment at a KDTF more than 70% of the time. Rather, on-site dialysis complements those services by providing the most accessible and best care for patients during the time they reside in a SNF.

As previously stated, CMS has issued their own updated guidelines<sup>3</sup> that supports on-site, staff-assisted, den-based HHD within a SNF, which is governed by HHD regulations that are traditionally exempt from CN.

#### **About DaVita, Inc.**

DaVita is a leading provider of 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. Much of DaVita’s success in providing outpatient dialysis services is rooted in its commitment to quality, with more than 95% of its programs rated 3+ stars by CMS. We are now bringing that same commitment to safe, high-quality dialysis services to patients residing in SNFs, delivering a triple-aim solution for our patients and partners.

#### **About Avalon Health Care Group**

Avalon Health Care Group is a post-acute healthcare services provider that offers skilled nursing, therapy, long-term care, residential care, and other medical services through our owned, operated, or managed facilities. Avalon currently provides care to patients and residents in California, Hawaii, Nevada, Oregon, Utah, and Washington. Avalon’s innovative approach allows them to work with Acute Care and community providers to partner in Post-Acute Care Collaboratives, participate in Bundled Payment Initiatives, and develop specialized programs such as their in-house Dialysis units in Utah and expanding to other regions soon.

#### **SNF Dialysis Patient Need**

Approximately one in ten dialysis patients in the United States resides in a skilled nursing facility (SNF) and each year 17 percent of the nation’s 600,000 dialysis patients will spend time in a SNF. Currently, most SNF residents who require dialysis are transported off-site to an in-center dialysis facility to receive treatment. The Center for Medicare and Medicaid Services (CMS) has recognized that providing dialysis on-site in the SNF leads to a better care experience for the patient, eliminates transportation costs, and can lead to improved clinical outcomes. Guidance from CMS released in March of this year (QSO-18-24-ESRD) provides validation of the “dialysis den” model of care and provides clear guidelines to ensure that the quality and safety of dialysis care in the SNF setting are “equivalent to the standards of care

provided to dialysis patients receiving treatments in a dialysis facility.” All DaVita provided on-site dialysis services are associated with a licensed and certified HHD program and comply with CMS Conditions for Coverage.

On-site dialysis in a SNF is considered to be “Home Dialysis,” as the treatment is delivered where the patient resides. Due to the unique needs of this patient population, DaVita provides “staff-assisted” HHD, a variation on the traditional “outpatient” HHD. The traditional home dialysis patient is high functioning and independent, and can perform the dialysis treatments either alone or with a care partner, who is often a family member. SNF residents who require dialysis are rarely able to perform self-care, and this vulnerable population requires the services of fully trained and dedicated dialysis staff, who function at the same level of training and expertise that patients would find at an ICHD facility.

In addition to offering patients safe and high-quality dialysis care, on-site SNF dialysis eliminates six transitions of care per week, as patients no longer leave the SNF to travel to an in-center facility. This results in fewer interruptions in medication and meal schedules and allows greater opportunities for the SNF resident to receive other care, such as physical and occupational therapy. The den model of dialysis, in which patients receive treatment in a common multi-treatment room, has been demonstrated to reduce hospital readmissions by 15%. Programs providing three-times-weekly treatment with conventional dialysis equipment have demonstrated a 14-day readmission rate less than a third of “more frequent dialysis” programs utilizing “home equipment,” demonstrating the importance of offering this standard of care to SNF residents.

#### **Description of Avalon Care Center - Federal Way SNF Dialysis Project**

- We are proposing a SNF home hemodialysis program in Federal Way, Washington at Avalon Care Center - Federal Way.
- As of 11/16/2023 Avalon Care Center - Federal Way has 104 residents, and is certified for 112 beds. Currently serving 9 ESRD patients who are being transported for treatment.
- The dialysis “den” would be built out by the SNF with sufficient physical plant requirements to support clinical quality equal to or exceeding that of outpatient dialysis care, as required by CMS
- Avalon Care Center - Federal Way will contract with DaVita, to provide equipment and dialysis-trained registered nurses and patient care technicians to deliver staff-assisted home hemodialysis. Contract dialysis RNs and PCTs will be prepared to complete any other requirements that Avalon Care Center - Federal Way requires of contract staff.
- The SNF home hemodialysis program will be operated as part of a Washington-licensed and CMS-certified HHD facility.
- The SNF home hemodialysis program would deliver home hemodialysis services exclusively to residents of the SNF. Patients maintain their choice of provider and modality and are eligible to treat at an in-center hemodialysis unit, or receive alternative home therapies (e.g. peritoneal dialysis) to the extent that they are supported by the SNF.

#### **Requested Determination of Reviewability**

While our proposed SNF dialysis program utilizes many of the same personnel, processes, and equipment as ICHD facilities in the pursuit of the best possible patient outcomes, the program provides HHD treatment ONLY to residents of the SNF, and thus should not be subject to CN review:

**ELIGIBILITY ARGUMENTS - As stated above, we believe that on-site SNF dialysis should be considered non-reviewable for the following reasons:**

- According to CMS the modality is HHD, which is already non-reviewable.
- The need forecasting methodology for KDTF determines station need for in-center hemodialysis, based on utilization of in-center kidney dialysis stations.
- In the SNF dialysis setting, stations are not built for maximum utilization, but rather to ensure that RN labor is efficiently utilized and to contain costs for the SNF provider, as well as payors and the overall Washington healthcare system (e.g. Washington Medicaid).
- A typical DaVita SNF dialysis program will utilize approximately 50% of theoretical capacity (6 shifts), but a common den size of 6 chairs balances RN capacity and the need for closer attention to this patient population.

*Additional Note: Though we believe this proposal to be non-reviewable because it is HHD, Washington also recognized the need to create [CN Exceptions](#) in cases when stations are located reasonably close to the people they serve, and SNF dialysis is always fulfilling this requirement.*

**CLINICAL NECESSITY - For the patient population in a SNF, a den model staffed by trained personnel provides the safest and highest quality care:** Previous SNF dialysis programs were deemed CN-reviewable not because of arguments around the volume of ICHD patient need, but rather because of assumptions made about which operational aspects distinguish HHD and ICHD modalities. Some aspects of Den-based HHD models operate more similarly to ICHD than traditional HHD services in the interest of patient experience, clinical quality, and cost of care.

Through communications with CN staff and our research, it seems the areas of concern with our model may be the following	Why our approach is better for patients
<p><b><i>CN staff assert “the provider will not have the ability to provide any in-center level of services.” DaVita was unable to find the WAC stipulating this, but we propose having the option to deploy in-center-grade equipment, policies, procedures in support of safe, high-quality care</i></b></p>	<ul style="list-style-type: none"> <li>• CMS regulations require that home dialysis services “are at least equivalent” to the care provided in-center</li> <li>• <u>Our model has demonstrated a 72% reduction in hospital readmissions within 14 days compared to SNF dialysis models utilizing “home” equipment and more frequent dialysis (delivered at bedside or in a den)</u></li> <li>• Allowing access to the best available equipment (machines, water treatment, etc.) permits the best quality and safety for the patient</li> </ul>
<p><b><i>Instead of requiring that SNF staff not be dialysis staff, SNF will contract with fully trained and licensed/certified dialysis personnel to provide treatment</i></b></p>	<ul style="list-style-type: none"> <li>• Per CN staff communications, it’s acceptable for SNF contracted staff to provide dialysis services</li> <li>• DaVita and its staff <u>are</u> contractors in this proposed structure, operating under a coordination agreement with the SNF</li> <li>• Our dialysis staff receive 360 hours of dedicated training for the SNF setting, in addition to any training completed for in-center or traditional HHD settings</li> </ul>

	<ul style="list-style-type: none"> <li>Fully trained dialysis providers are better able to respond to complications during dialysis, particularly with the greater clinical complexity often present in the SNF population</li> </ul>
<p><b><i>Instead of individual treatment in single patient rooms (1:1), we propose using a “den” treatment room</i></b></p>	<ul style="list-style-type: none"> <li>The definition of a “kidney dialysis facility” is simply “any place...equipped and operated to provide services”<sup>4</sup> – this could describe either a SNF resident’s room (which has been non-reviewable for CN) or a den setting, so SNF dialysis dens could also be considered non-reviewable</li> <li>By regulation, dialysis requires constant immediate supervision of the patient by the dialysis provider; the den setting allows for immediate supervision of multiple patients by both an RN and PCT – equal to or exceeding the level of supervision provided in the outpatient setting, as required by CMS</li> <li>Supervision of patient care technicians by a licensed dialysis RN is critical to patient safety and quality of treatment, and is more challenging to operationalize efficiently in SNF resident rooms</li> <li>Better utilization of scarce RN resources (in the den setting vs. 1:1 bedside) allows for better access to care for more patients</li> <li>Dens equipped with conventional dialysis equipment allow patients to receive the same schedule of care to which they are accustomed</li> </ul>
<p><b><i>SNF dialysis programs are required to have backup care available and the ability to transfer patients to CN-approved providers or hospitals. As an entity, DaVita is also a CN-approved provider</i></b></p>	<ul style="list-style-type: none"> <li>With DaVita’s status as a CN-approved provider, we are best able to coordinate backup care or in-center transfers with either DaVita or other in-center/acute facilities</li> </ul>

***CMS COMPLIANCE - This project and model are fully in compliance with CMS regulations, whereas current WAC guidelines encourage models that are not in compliance or introduce significant risk to patients:*** DaVita SNF Dialysis complies with the latest CMS regulations on SNF dialysis (QSO-18-24-ESRD)

- Must be under care of a certified licensed dialysis provider
- Home dialysis services “are at least equivalent” to the care provided in-center
- May be administered by dialysis facility staff under a coordination agreement between the SNF and dialysis provider
- Any other dialysis provider must be trained, competent and knowledgeable; determination of competency is made by the ordering nephrologist
- Provide qualified dialysis TM to remain in the room, with visual line of sight to the patient’s dialysis access for the entire dialysis treatment

- Because SNF dialysis falls under home dialysis, a brick and mortar training facility must be available for licensure and certification purposes

DaVita brings significant capabilities to ensure regulatory compliance and high reliability for patient safety:

<b>Oversight</b>	<ul style="list-style-type: none"> <li>• Policies &amp; Procedures</li> <li>• Teammate staffing/training, competencies, licensing and documentation</li> <li>• Performance Improvement Programs</li> </ul>
<b>Water Quality</b>	<ul style="list-style-type: none"> <li>• Cultures</li> <li>• LAL</li> <li>• Chloramine</li> <li>• AAMIs</li> </ul>
<b>Bio-medical</b>	<ul style="list-style-type: none"> <li>• 24/7 coverage</li> <li>• Technical support &amp; training</li> <li>• Repair &amp; Maintenance of water system and machines</li> <li>• Water system &amp; machine disinfection</li> <li>• Emergency response (supplies /water/water free machines)</li> </ul>
<b>Quality metrics</b>	<ul style="list-style-type: none"> <li>• Defining</li> <li>• Data collection</li> <li>• Data analysis</li> <li>• Data reporting</li> </ul>
<b>Infection control</b>	<ul style="list-style-type: none"> <li>• Hepatitis B</li> <li>• CVC care</li> <li>• PPE</li> </ul>
<b>Additional</b>	<ul style="list-style-type: none"> <li>• Supply acquisition</li> <li>• Emergency &amp; Disaster planning</li> <li>• Vascular Access, Cannulation, Hemostasis, and Care</li> </ul>

If you have any questions about this project, or if the Department wishes to have any additional information to make a determination on our request, please do not hesitate to contact us.

Sincerely,



Brad Oglevee  
 Division Vice President  
 DaVita, Inc.  
 Brad.Oglevee@davita.com



Samantha Wachowski  
 Executive Director, Avalon Care Center – Federal Way  
 Avalon Healthcare, Inc  
 Samantha.Wachowski@avalonhealthcare.com

1 - WAC 246-310-812(2) Data used to project station need must be the most recent five-year resident end-of-year in-center patient data available from the Northwest Renal Network as of the letter of intent submission date, concluding with the base year at the time of application.

2 - CN Methodology (3) Projected station need must be based on 4.8 resident in-center patients per station (4.8 planning area) for all planning areas except Adams, Columbia, Douglas, Ferry, Garfield, Jefferson, Kittitas, Klickitat, Lincoln, Okanogan, Pacific, Pend Oreille, San Juan, Skamania, Stevens, Wahkiakum, and Whitman counties. The projected station need for these exception planning areas must be based on 3.2 resident in-center patients per station (3.2 planning area).

3 - QSO-18-24-ESRD

4 - WAC 246-310-800(10) (10) "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. (19) "Resident in-center patients" means in-center hemodialysis (HD) patients who reside within the planning area. If more than fifty percent of a kidney dialysis facility's patients reside outside Washington state, these out-of-state patients would be considered resident in-center patients.

5 - 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).