

Received 05/06/22-KN

April 27, 2022

Via Email

Certificate of Need Program Washington State Department of Health Attn: Eric Hernandez, Program Manager PO Box 47852 Olympia, WA 98504-7852

Dear Mr. Hernandez:

I am writing on behalf of Prestige Care, Inc. to request a determination of reviewability, pursuant to <u>WAC 246-310-050</u>, that the addition of home dialysis services at Care Center (Hazel Dell), Inc. DBA – Discovery Nursing & Rehabilitation of Vancouver is not subject to CN review.

About Prestige Care, Inc.

- Prestige Care was founded in 1985 as a family company, however, the origins go back to 1946 to Sarah Delamarter who opened her first home to care for seniors to provide a means to support her family. Her commitment to care of seniors has now passed down throughout her family, and, has grown to over 80 centers in the Northwest, with an eye to keeping Sarah's dedication to care as the Top Priority.
- Prestige is a family company who offers a complete senior care organization that includes independent living communities, assisted living, memory care, as well as skilled nursing and rehabilitation centers.
- Prestige Care has a promise to touch lives every day. It's a philosophy of caring and is based on our core values of, Respect, Integrity, Commitment & Trust, which are at the center of all that we do.
- Prestige is also committed to diversity, and a strong promote-from-within culture, ensuring that our people continue Sarah Delamarter's mission to provide compassionate care for seniors under our care.

Description of Additional Services

• The proposal is to add home hemodialysis services ("HHD") for the residents of Discovery Nursing & Rehabilitation of Vancouver located at the following address:

5220 NE Hazel Dell Avenue Vancouver, WA 98662

- To support the additional service, Prestige Care will build out a designated area within the nursing home for residents to comfortably receive dialysis treatments. The estimated total cost to create this space and add the service is \$250,000.
- In accordance with CMS regulatory guidance, Prestige Care will contract with DaVita, Inc. to provide home dialysis services to residents.¹ A draft of the agreement has been included as Appendix A, which outlines the roles and responsibilities of each party involved in sections 3 and 4. Key delineations of responsibilities is as follows:
 - Prestige Care is responsible for the sole cost and expense of providing a safe environment for dialysis treatments within the nursing home for residents requiring HHD services.
 - DaVita is responsible for providing qualified and licensed personnel to perform HHD treatments and to provide HHD services through an existing CMS licensed HHD program.
- The services will be provided under an existing CMS licensed HHD program and will be billed and reimbursed as traditional HHD treatments.
- The HHD services will be exclusively available to residents of Discovery Nursing & Rehabilitation of Vancouver. Residents will simply walk or be transported to a designated area within their nursing home and receive treatment from a trained HHD RN provided by DaVita without needing to leave the premises.
- The proposed service will be incapable of providing in-center hemodialysis services as the infrastructure of the area within the SNF will be unable to support traditional in-center hemodialysis and the program will not be licensed to provide outpatient treatments.
- The proposed services will not have an impact on the existing bed capacity at Discovery Nursing & Rehabilitation of Vancouver.

Requested Determination of Reviewability

The Department may require a CN only for those activities identified in the CN statutes. CN-reviewable activities include:

- a) "Any expenditure for 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 subject to the provisions under chapter 246-310 WAC," Per RCW 70.28.025(4)(g) and WAC 246-310-020(1)(g).
- b) "Any increase in the number of dialysis stations in a kidney disease center," Per RCW 70.28.025(4)(h) and WAC 246-310-020(1)(e).

An analysis of each relevant CN activity is provided below.

a) Expenditure for Change in Nursing Home Services

A CN is required if the expenditure for a change in nursing home services is in excess of the expenditure minimum established pursuant to WAC 246-310-900. The latest nursing home capital expenditure threshold was Updated December 2019 and is set at a minimum of \$2,834,165.²

Prestige Care is proposing to add home dialysis services at Discovery Nursing & Rehabilitation of Vancouver with an estimated total cost of \$250,000 well below the expenditure threshold minimum. The cost will be entirely funded by Prestige Care as outlined in the contract included in Appendix A.

Certification/SurveyCertificationGenInfo/Downloads/QSO18-24-ESRD.pdf

² https://doh.wa.gov/sites/default/files/legacy/Documents/2300/2020//2019-2020NHCapitalExpend.pdf

¹ https://www.cms.gov/Medicare/Provider-Enrollment-and-

The estimated cost to add HHD services is below the expenditure threshold minimum and, therefore, a CN is not required.

b) Increase of dialysis stations in a kidney disease center

Prestige Care Discovery Nursing & Rehabilitation of Vancouver is a nursing home, not a kidney disease center. 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." The home dialysis service that is being proposed does not fall within this definition as outpatient dialysis services in the SNF are neither provided nor possible. The service will be exclusively available to patients whose home is the SNF. In their 2018 letter to surveyors, CMS specifically defines and refers to this type of service as "Home Dialysis in a Nursing Home."³

Adding home dialysis services at Prestige Care Discovery Nursing & Rehabilitation of Vancouver will not increase dialysis stations in a kidney disease center as the facility is a nursing home and, therefore, a CN is not required.

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,

Angela Ross Chief Strategy Officer Prestige Care, Inc. aross@prestigecare.com 360-901-9662

³ https://www.cms.gov/Medicare/Provider-Enrollment-and-

Certification/SurveyCertificationGenInfo/Downloads/QSO18-24-ESRD.pdf

Appendix A

Contract with DaVita

HOME HEMODIALYSIS COORDINATION AGREEMENT (DAVITA DIRECT STAFFING)

This Home Hemodialysis Coordination Agreement (this "Agreement") is made as of the Effective Date (as defined in Section 6) by and between Prestige Care, Inc., a Washington corporation ("Owner") and Total Renal Care, Inc., a California corporation and subsidiary of DaVita, Inc. ("Company").

RECITALS

A. Owner operates a nursing facility known as Discovery Nursing and Rehab of Vancouver, duly licensed in the State of Washington and located at 5220 NE Hazel Dell Ave, Vancouver, WA 98663(the "NF") and has full authority to effect uate this Agreement.

B. Owner desires to ensure the availability of home hemodialysis ("HHD") for those residents of the NF who require dialysis and who are appropriate candidates for HHD.

C. Company has a licensed (as necessary according to State law) and Medicarecertified End Stage Renal Disease ("ESRD") facility ("Facility") experienced and qualified to provide "Renal Dialysis Services", as defined at 42 C.F.R. § 413.171, and required by its Conditions for Coverage ("CFCs"), and as described herein, including necessary support and training to persons treating with the HHD modality, and clinical staff members of NFs (collectively, the "Services").

D. It is appropriate for Company to provide the Services to the NF's residents in a manner consistent with federal and state law, including, but not limited to, Medicare guidance related specifically to home dialysis in the nursing facility setting set forth by the Centers for Medicare and Medicaid Services ("CMS") in the State Operations Manual §§ 2270-2288 and Appendix PP § 483.25(1) (Tag F698), CMS Survey and Certification Group Memorandum No. 04-24 (Mar. 19, 2004), and CMS Quality, Safety, & Oversight Group Memorandum Nos. 18-22 (Aug. 10, 2018) and 18-24 (Aug. 17, 2018).

E. Only the attending nephrologist treating a resident's ESRD ("Nephrologist") can refer a resident to Company for Services and order HHD treatment. Company, Owner, or other physicians treating non-ESRD-related conditions are not authorized to refer residents for Services.

F. Owner desires to engage Company to provide the Services for residents of the NF who require HHD pursuant to an order from the resident's Nephrologist. Other than the Services explicitly described in this Agreement, Company shall have no responsibility for Owner's non-dialysis related staffing, care, monitoring, treatment, or other services provided to residents.

In consideration of the mutual promises herein, Owner and Company agree as follows:

AGREEMENT

1. <u>Incorporation of Recitals and Exhibits.</u> The recitals set forth above and all Exhibits and Schedules attached hereto are incorporated into this Agreement.

2. <u>Appointment of Company.</u> Owner appoints Company as its exclusive provider of Services during the Term (as defined below). Company accepts said appointment and agrees to provide the Services under and subject to the terms and conditions of this Agreement.

3. <u>Company Obligations</u>.

A. Company will provide the Services required to be provided by a certified ESRD facility under applicable regulations and in accordance with Company's policies and procedures to residents of the NF who: (i) require dialysis treatments for ESRD or Acute Kidney Injury ("AKI"), as ordered by a Nephrologist; (ii) are admitted appropriately to the Facility (as defined below) in consultation with Nephrologist, and; (iii) meet Company's admission criteria for HHD treatment in a NF (each, a "HHD Patient"). Company will not accept residents from the NF who do not meet all of these admission criteria. Further, Company will not accept patients for HHD treatment within the NF who are not residents of the NF.

B. Company will provide a Registered Nurse ("Company RN") to perform each HHD Patient's HHD treatments and a patient care dialysis technician (a "PCT"), as needed, to assist each Company RN. Each Company RN and PCT (collectively, "Company Staff") will meet applicable state and federal qualifications. The Company RN's competency will be approved by the dialysis Facility medical director and governing body. The Company RN will perform (i) all HHD treatments; (ii) the intravenous administration or injection of heparin, Epogen, or other medications as ordered by an HHD Patient's Nephrologist that are related to the Patient's ESRD condition; and (iii) the completion of other services consistent with HHD as set forth in Company policy. Only the Company RN may initiate or discontinue dialysis treatment, but the Company RN may also monitor a HHD Patient's treatment. Company will ensure that the Company RN is constantly present on-site at the NF and immediately present in the general area and readily available (if performing other duties) to respond to concerns or emergencies that may occur during an HHD Patient's HHD treatment. Company Staff will be present in the room at the NF and will maintain direct visual contact with the HHD Patient (including the HHD Patient's vascular access site and bloodline connections) at all times that HHD treatments are being performed. Company Staff will monitor the HHD Patient during dialysis treatments for complications possibly related to dialysis. Company Staff will be responsible for appropriately documenting the HHD treatment that the Company Staff provide to the HHD Patient

C. Company will provide the NF with the appropriate number of Company Staff during Normal Operating Hours (as defined below). Based upon the NF's HHD Patient volume, acuity level, and ability to treat in the designated "Treatment Den," Company will determine, in its sole discretion, the appropriate level of staffing necessary to provide safe and effective HHD treatments.

D. Company will decide whether and under what circumstances to provide treatment outside the designated Treatment Den in its sole discretion.

E. Company will provide the necessary Company Staff at the NF during its normal hours to provide Services to HHD Patients. If HHD treatments occur during the week of a holiday the Company observes, Company will ensure that HHD Patients are rescheduled as necessary depending on the impact of observed holidays on the HHD Patient's plan of care.

F. Company will maintain direct responsibility for the safety and quality of the Renal Dialysis Services provided to the HHD Patients admitted to the Facility, consistent with ESRD CFC requirements, the ESRD Prospective Payment System rules, as well as the terms of this Agreement. Company is responsible for the safe delivery of dialysis to the HHD Patient, including review of qualifications, training, competency verification, and monitoring of Company Staff. Company is responsible for the quality and safety of the dialysis treatments and the management of the HHD Patients' ESRD treatment-related conditions.

G. Company will provide each HHD Patient clinically appropriate and required HHD treatment, including a medical assessment, dietitian and social worker consultations, surveillance of home adaptation, a record keeping system which assures continuity of care, and patient care planning in association with the HHD Patient's Interdisciplinary Team ("IDT").

H. When the HHD patient arrives to the Treatment Den for HHD treatment, Company will have the sole responsibility for transferring the HHD patient to the dialysis treatment chair. After the HHD treatment is discontinued and the HHD patient can be safely transported from the Treatment Den, Company will transfer the HHD patient from the dialysis treatment chair to the Owner for transportation from the Treatment Den.

I. Company will provide and install equipment associated with HHD (*i.e.*, dialysis machines and portable water equipment), and will use commercially reasonable efforts to ensure that all such equipment is maintained in good working order, including testing and monitoring water and dialysate quality. Company will replace or restore any equipment that is non-functional to avoid interruption of a patient's dialysis treatment.

J. Company, in collaboration with Owner as needed, will develop and implement policies and protocols for the delivery of Renal Dialysis Services and Services that are equivalent to the standards of care provided to dialysis patients receiving treatments in a dialysis facility. These protocols will include requirements set forth at *42 CFR 494.30 and 494.80 through 494.100*, including procedures for infection control, patient assessment, patients' plans of care, and care of the dialysis patient at NF, and those outlined in the Medicare State Operations Manual §§ 2270-2288 and Appendix PP § 483.25(l) (Tag F698). Subject to the policies referenced in Section 5.H **Error! Reference source not found.**, Company internal policies and procedures will govern the clinical aspect of Renal Dialysis Services Company provides and Company will adhere to such policies and procedures.

K. Company will not provide Renal Dialysis Services or Company Staff to any NF resident not admitted to the Facility or for whom Company has not confirmed third-party payor

insurance. Company will not provide any Renal Dialysis Services for a NF resident until after the resident is admitted to the Facility and Company, and Company has followed its required processes to begin HHD treatments. Company will not be obligated to provide Renal Dialysis Services to NF residents beyond those outlined herein, and as appropriate and required for HHD Patients dialyzing in the home setting, as determined by the Company.

L. Company will provide such Renal Dialysis Services through the following Company outpatient ESRD Facility:

Vancouver Dialysis 9120 NE Vancouver Mall Drive, Suite 160 Vancouver, WA 98662-9401

M. Consistent with consolidated billing requirements applicable to NF residents, i.e., Section 1861(s)(2)(F) and (2)(O) of the Social Security Act, Company will bill applicable third-party payors for all Renal Dialysis Services provided by Company to HHD Patients that can be appropriately billed by Company, except for Company RN and PCT services, which will be billed to Owner in accordance with Sections 4.A and 4.B.

- (i) Company will bill Owner, and Owner will reimburse Company, for all Services and supplies provided hereunder that are not included in any thirdparty payor reimbursement paid to Company (including, but not limited to, Company RN and PCT services and patients who are not residing in a skilled nursing facility bed).
- (ii) Company will not be obligated to provide any services or supplies hereunder which are not (1) included under a bundled rate or prospective payment system reimbursement or included in any third-party payor reimbursed or (2) reimbursed to Company by Owner.
- (iii) Owner will provide Company with all requested HHD Patient and payor information to facilitate any third party billing.

N. Company will communicate with Owner regarding all required supportive care of the HHD Patient both during and after dialysis treatment (e.g., respiratory therapy, monitoring combative patients, weight, dietary/fluid intake, and other conditions related to fluid overload/depletion/infection/electrolyte imbalance post-dialysis). Company Staff will provide required supportive care during dialysis treatment and NF will be responsible for providing required supportive care outside of dialysis treatment.

O. Company will communicate with Owner as urgent patient-care issues arise, and take remedial action where appropriate. Company will collaborate with Owner as necessary to provide dialysis care coordination to each HHD Patient admitted to Facility to receive HHD treatments. Communication procedures will allow for 24/7 communication between the Company and Owner. Company will provide to the Owner a telephone support and a list of names and contact information of Nephrologist and/or Company RNs to be called for emergencies; however,

Company RN will not be available to come on-site to NF outside of Normal Operating hours. Company is not responsible for the Nephrologist availability or response outside of their monthly visit with the HHD Patient. In the event of an urgent ESRD-related issue outside of Normal Operating Hours, the Owner will be responsible for transportation to outpatient facility or hospital.

P. Company will maintain overall responsibility to prepare NF staff to address emergencies and/or complications related to the dialysis needs of the HHD Patient receiving treatments in the NF. Any training necessary for NF staff will be administered under the direction of a Company RN meeting the qualifications at $42 \ C.F.R \ 494.140(b)(2)$. Company RN will train NF staff periodically on basic dialysis-related care of HHD Patient (e.g., fluid and dietary restrictions, care and monitoring of dialysis access between treatment, and monitoring residents pre- and post-dialysis for complications related to the dialysis treatment such as symptoms of fluid overload or depletion, infection, and electrolyte imbalance). Company and Owner will maintain documentation of completion of NF staff training as needed.

Q. Company will ensure a backup plan is in place to ensure that HHD Patients receive treatment if a situation occurs where the NF cannot provide a safe and sanitary environment for dialysis treatments. NF will immediately notify the Company that the NF cannot provide a safe environment for dialysis treatments and Company will make reasonable efforts to provide the dialysis treatments at a backup location to avoid delay or cancellation of treatment.

R. Company will use commercially reasonable efforts to maintain a reserve of supplies to be available in emergency circumstances (e.g., natural disasters, staff shortages, lack of appropriate supervision, etc.). Company will ensure the emergency supply reserve is in excess of routine supply inventory. Company will order and provide Owner with medications, equipment, and dialysis related supplies through routine deliveries, and collaborate with Owner on plan for the delivery of additional supplies if an emergency occurs.

S. Company will review treatment records to ensure accurate documentation of delivered dialysis treatments and effects on the HHD Patients during dialysis, including adverse events.

T. As part of the periodic review and support of HHD Patients by Company's IDT, Company will arrange for each HHD Patient to consult with a qualified social worker and a qualified dietitian during their scheduled visits to the Facility. Such scheduled visits will occur monthly. Company dietitians will be available to provide dietary support to the NF's dietary staff and primary care team regarding the renal diet of individual HHD Patients, as ordered by the resident's Nephrologist. Company's social worker will coordinate with the NF's social worker, and Company's social worker will be involved in an HHD Patient's overall care plan regarding dialysis issues.

U. Company will arrange for the provision of all laboratory tests considered Renal Dialysis Services included in any bundled rate or prospective payment system reimbursement received by Company or that are separately billable by the testing lab ("ESRD Tests") as ordered by an HHD Patient's Nephrologist. Company will monitor lab values related to dialysis and act

upon values as needed. ESRD Test results will be available to the NF's attending staff the next business day following Company's receipt of such results.

(i) Company may, but will not be required to, conduct any laboratory tests that are unrelated to an HHD Patient's ESRD condition ("Non-ESRD Tests") as ordered by an HHD Patient's Nephrologist or Physician. Such Non-ESRD Tests will be conducted according to Company's routine procedures and at the laboratory's standard rates. Company will bill third-party payor for Non-ESRD Tests that can be appropriately billed by Company. If Patient has third party payor coverage where Non-ESRD Tests are payable to Owner, Company will bill the Owner directly for any Non-ESRD Tests since the Non-ESRD Tests are reimbursed as part of the Owner's consolidated billing requirement.

V. Company will ensure the HHD Patient engages in monthly visits with his or her Nephrologist and will provide to Owner any orders received from HHD Patient's Nephrologist regarding the dialysis prescription, medications, and diet. Company will follow the dialysis prescription, provide Renal Dialysis Service medications, and communicate all changes in the orders to the Owner. Company will communicate with Owner any necessary post-treatment monitoring required of the NF (monitoring weight, dietary/fluid intake, and other conditions related to fluid overload/depletion/infection/electrolyte imbalance post-dialysis).

Company will maintain and submit all required documentation to the appropriate ESRD network.

4. <u>Owner Obligations</u>.

A. Company will bill owner the treatment rates ("Treatment Rates") set forth in <u>Exhibit A</u> ("Treatment Rate Schedule"). Owner agrees to pay Company the Treatment Rates. The Treatment Rate Schedule will be consistent with fair market value. On the first (1st) anniversary of the Effective Date, and on each anniversary thereafter, the Treatment Rate Schedule on Exhibit A will be increased by two percent (2%) for the Term of the Agreement.

B. <u>Payment</u>. On or before the tenth (10th) day of the month following the month in which the Renal Dialysis Services are provided, Company will bill Owner in accordance with the Treatment Rate Schedule in <u>Exhibit A</u>. Owner will review and pay any amounts not disputed within 30 days of the month following the month in which the Services were provided. If Owner disputes any items, Owner will notify **chargemasters@davita.com** and specify the invoice line items under dispute along with documentation explaining why Owner is disputing such line items. The parties will first attempt to resolve any disputed items using the dispute resolution process set forth in Section 17.A. If after 30 days the parties do not resolve the dispute item(s), the parties shall submit to the dispute resolution process set forth in Section 17.B below. Outstanding balances not paid within 60 days of the invoice date will be subject to late fees at a rate of 1½ percent per month. Any outstanding balance not received by Company within 60 days of the invoice date will constitute a material breach of this Agreement. Owner agrees to pay all costs and expenses (including reasonable attorneys' fees) incurred by Company for the collection of fees owed by Owner.

C. At its sole cost and expense, Owner will provide a designated Treatment Den, including without limitation dialysis treatment chairs, patient scale, furniture, and crash carts, for Company's exclusive use in providing Renal Dialysis Services here. Prior to the commencement of Renal Dialysis Services, such Treatment Den, as well as any subsequent changes or modifications to the Treatment Den during the Term, routine maintenance excepted, must be approved in advance by Company in its sole, reasonable discretion. It shall be Owner's responsibility to ensure such Treatment Den is at all times: (i) compliant with all applicable Laws, rules, and regulations, including licensure and certification requirements, and (ii) of a quality and size necessary for Company to provide the Services based on Company's standards, practices, procedures, and guidelines at Company's sole, reasonable discretion.

D. Owner will ensure that the NF is at all times a Skilled Nursing Facility or Nursing Facility as licensed by the state of Washington.

E. NF staff will not provide or assist with providing dialysis treatments to HHD patients.

F. Owner will provide a safe and sanitary environment for the dialysis treatments. Owner will monitor the HHD Patient before and after dialysis treatments for complications possibly related to dialysis. Owner will provide basic dialysis-related care to HHD patients before and after dialysis treatments. Owner will provide all non-dialysis related care. NF staff will be prepared to appropriately address and respond to dialysis-related complications and provide emergency interventions as needed. NF will be responsible for providing emergency care required during dialysis treatment as well as outside of dialysis treatment. *See 42 CFR 483.25(l) and SOM App. PP at tag F698*.

G. Owner shall have the sole responsibility for transporting HHD Patients to and from the Treatment Den within the NF to receive dialysis treatments at the scheduled time. If an HHD Patient is more than 30 minutes late for an appointment or misses an appointment because of a lack of transportation to and from the Treatment Den, Company will determine if the HHD Patients can be safely treated when they arrive at the Treatment Den or Company will reschedule their treatment.

H. Owner will notify Company immediately of any dialysis-related complications and provide any orders for treatment obtained from an HHD Patient's Nephrologist upon receipt thereof if not directly provided to Company Staff. Owner will communicate with Company as issues arise, and take remedial action when appropriate. If a situation occurs where the Owner cannot provide safe and sanitary environment for dialysis treatments, the Company will be notified and provide the dialysis treatments at a backup location to avoid delay or cancellation of treatment.

I. Owner will have sole responsibility for providing or arranging transportation of HHD Patients to and from the Facility to receive Services, as necessary if the HHD treatment and/or training cannot be performed at the NF, or as requested by the Owner. The NF will be responsible for HHD Patients during such transportation.

J. Owner will ensure NF staff collaborates with Company as necessary to provide

dialysis care coordination to each HHD Patient admitted to the Facility to receive dialysis treatments. Owner will have opportunity to assist Company in developing and implementing protocols for the delivery of ESRD services that are equivalent to the standards of care provided to dialysis patients receiving treatments in a dialysis facility. These protocols will include requirements set forth at 42 CFR 494.30 and 494.80 through 494.100, including procedures for infection control, patient assessment, patients plans of care, and care of HHD Patients.

K. With direction by Company Staff, Owner will administer all ordered Renal Dialysis Service medications necessary for HHD Patients that are not administered during the course of dialysis treatment. Company will provide to NF any Renal Dialysis related medications requiring administration outside of the HHD patient's dialysis treatment.

L. Owner remains responsible for the overall quality of care that its residents receive and retains sole responsibility for the appropriate care and treatment of all HHD Patients while such persons are not in the Facility. Owner's licensed nursing staff will receive and implement all treatment orders from Nephrologists promptly, including, without limitation, the intravenous administration or injection of all medications as ordered by an HHD Patient's Nephrologist that are unrelated to the Patient's HHD treatment. NF staff will provide ongoing assessment of the HHD Patient before and after HHD, including vital signs, level of consciousness, muscle cramping, itching and comfort or distress, or problems with the HHD Patient's access site; and must report identified or suspected complications to the Nephrologist and identified Company Staff to enable timely interventions.

M. Owner will provide Company adequate, segregated, secure, and refrigerated storage space for all necessary individual HHD Patient supplies, equipment and medication to prevent any delays or interruptions to a HHD Patient's prescribed dialysis treatment, and – in collaboration with the Company – ensure a reserve of supplies are available in emergency circumstances ("Storage Space"). Owner will timely return all supplies and equipment to Company in these circumstances: (i) NF resident ceases HHD treatment with Owner, or (ii) this agreement is terminated. Prior to the commencement of Services hereunder, such Storage Space, as well as any subsequent changes or modifications to the Storage Space during the Term, routine maintenance excepted, must be approved in advance by Company in its sole, reasonable discretion.

N. Owner will ensure that it has access to medications and treatments such as antibiotics and intravenous fluids to treat common complications of dialysis. The NF staff will collaborate with the NF medical director, consultant pharmacist, and Company to develop policies and procedures to address common complications and to ensure access to needed medications.

O. If a HHD treatment is postponed or canceled, NF staff will monitor and document the HHD Patient's response to the postponed or canceled treatment, including monitoring and medical management of for changes such as fluid gain, respiratory issues, review of relevant lab results, and any other complications that occur until dialysis can be rescheduled based on HHD Patient assessment, stability, and need.

P. Nothing in this Agreement is intended to limit or restrict the Owner's ability to admit any potential NF patient requiring dialysis. If Owner admits a NF resident anticipated to

become a HHD Patient, Owner will coordinate with Company to ensure such NF resident is admitted appropriately to the Facility and meets Company's admission criteria for HHD treatment in a NF. Owner will inform such NF resident of the relationship with Company under this Agreement prior to admission to the Facility in order for the NF resident to choose his or her provider for dialysis services. If Owner admits a NF resident who is already receiving HHD treatment through another ESRD facility by a trained caregiver that is not Company or NF staff, Owner will communicate this to Company. For NF residents not admitted to the Facility because they do not meet the Company's HHD admission criteria (*e.g.*, a NF resident with AKI or ESRD who has no third-party payor insurance) or the NF resident declines to treat with Company, Owner will be solely responsible for ensuring patients are transported to and from an appropriate off-site ESRD facility.

Q. Owner will ensure HHD Patients' Nephrologists can round on their HHD Patients as necessary without additional credentialing beyond what is required by Company.

R. If an emergency arises regarding an HHD Patient that requires hospitalization, the HHD Patient will be transferred to the hospital with which the Owner has a transfer agreement. To the extent the NF has no hospital transfer agreement in place or the hospital indicates it will not accept the HHD Patient, the HHD Patient will be transferred to a hospital with which Company has a transfer agreement.

S. If an HHD Patient is transferred to a hospital (regardless of the basis for the transfer), Owner will promptly inform Company of the transfer, including the date of the transfer and the date (if any) the patient returns to the NF.

T. If an HHD Patient is discharged from the NF, Owner will provide Company with notice of the HHD Patient's discharge and will coordinate with Company regarding the HHD Patient's ongoing dialysis care. Further, Owner will ensure any supplies, equipment and medications Company has provided for the HHD Patient's use is immediately returned to Company.

U. Owner may, but will not be required to, provide entertainment (e.g., television, movies, local telephone access, shared internet access, reading materials) in the Treatment Den that is made available to all HHD Patients.

V. Owner will be responsible for the maintenance of its own equipment which is not provided by Company.

W. Owner will provide janitorial, laundry, and environmental services, all as related to the Services including, without limitation, medical and hazardous waste removal.

X. Owner will provide utilities including electricity, gas, and HVAC. Additionally, Owner shall provide access to sufficient dedicated GFI electrical outlets necessary for the proper functioning of dialysis equipment any other electrical device that may be required for patient care.

Y. Owner shall provide telecommunications including emergency call systems. Telephone and fax lines will include outside line usage located in the space provided for the

provision of Renal Dialysis Services. Owner shall provide to Company Staff direct access to the public internet via a publicly routable IP address that is assigned to Company by Owner's Internet Service Provider or a private IP address from Owner network with appropriate accommodations made on Owner's internet firewall to allow connectivity to Company's VPN. Company will pay (or reimburse Owner) for the connectivity charges and network change requirements.

Z. <u>Proprietary Rights</u>. The manuals, software, systems, methods, procedures, policies, controls, documents and pricing and the information relating thereto (including without limitation purchase orders and all form documents) and all information relating to Company and its Affiliates, including without limitation, the financial condition, marketing plans, regulatory affairs, and business strategies of Company or its Affiliates, employed or obtained by Company or its Affiliates and all trademarks, service marks, tradenames, copyrights and other proprietary rights in which Company or any of its Affiliates has any interest (collectively, "Company's Proprietary Rights") are proprietary to Company and shall remain the property of Company and are not, at any time during the Term of this Agreement or thereafter, to be utilized, distributed, disseminated, copied or otherwise employed or acquired by Owner or any of Owner's Affiliates, shareholders, Members, agents or employees, except as authorized by Company in writing.

- (i) Owner acknowledges that the breach of the provisions of this Section 4.Z would cause irreparable injury to Company that could not be adequately compensated by money damages. Accordingly, Company may obtain a restraining order, injunction or other equitable relief prohibiting a breach or threatened breach of the provisions of this Section 4.Z without the necessity of posting any bond or security whatsoever, in addition to any other legal or equitable remedies that may be available. In the event of a breach or threatened breach by Owner of any of its obligations under this Section 4.Z, Company shall have the right, in addition to any other remedies which may be available to it, to obtain specific performance of the terms of this Agreement without posting any security or bond whatsoever, and Owner hereby waives the defense that there may be an adequate remedy at law.
- (ii) If requested by legal process to disclose any information constituting any of Company's Proprietary Rights, Owner shall promptly give notice of such request or requirement to Company so that Company may, at its own cost and expense, seek an appropriate protective order or, in the alternative, waive compliance to the extent necessary to comply with such request if a protective order is not obtained. If a protective order or waiver is granted, Owner may disclose such information only to the extent required by such court order or to the extent permitted by such waiver.

The provisions of this Section 4.Z shall survive the termination of this Agreement.

5. <u>Company and Owner Coordination.</u>

A. Company will collaborate with NF staff to develop and implement an individualized care plan based on a patient's assessment. Company and NF staff will collaborate

to monitor and address any medical or non-medical needs of HHD Patients that are identified, and will communicate to ensure that the provision of emergency care during dialysis is provided in accordance with the HHD Patient's wishes and advanced directives. NF will be responsible for providing emergency care required during dialysis treatment as well as outside of dialysis treatment. Company and Owner will communicate to ensure documentation of assessments, care provided, and interventions by both parties are complete, timely, and accurate. Owner will have opportunity to coordinate with Company staff on an individualized care plan based on the patient's assessment.

B. Company and NF staff will communicate on any barriers or issues preventing HHD Patients from meeting their established Facility goals, and barriers will be reassessed by both Company's IDT and NF staff and documented in an updated plan of care. Company and Owner will review NF and ESRD plans of care and make collaborative revisions to ensure that the HHD Patient's needs are met and their goals are attained. Owner and Company's social workers, dieticians, and nurses will engage in ongoing communication regarding the HHD Patient's condition and treatments, including face to face meetings as necessary.

C. Company and Owner will maintain communication regarding the safety and cleanliness of the nursing home dialysis environment and resolution of any related issues. Company and Owner will communicate to provide a safe and sanitary environment for dialysis including communication on: infection control practices, room type specifics (isolation/roommate selection), monitoring/mitigating hazards, prohibiting intrusions into dialysis environment during treatment, cleaning/disinfecting all dialysis equipment and usable supplies, and protecting the personal dialysis equipment/supplies of the HHD Patient from unauthorized access.

D. Company and Owner will coordinate to ensure the initial and on-going verification of competencies of any dialysis administering personnel or caregivers, including documented evidence of Company Staff qualifications, prior to the start of initiation of patient care. Training and competency verification records for Company Staff will be maintained by Company and Owner.

E. Company and Owner will communicate to ensure incorporation of the Renal Dialysis Services provided to HHD Patients into the Facility's Quality Assessment and Performance Improvement ("QAPI") program. The QAPI program will include at least: 1) monitoring HHD Patient outcomes in clinical areas; 2) technical operations; 3) water and dialysate quality; and 4) adverse events. Company and Owner will ensure the immediate reporting of any unexpected/adverse events during dialysis to the HHD Patient, his or her Nephrologist, NF staff, and their responsible party.

F. If a dialysis treatment is postponed or canceled, Company and Owner will ensure that the nephrologist and attending practitioner are notified. Company and Owner will develop a systematic approach to handling situations where an HHD Patient has a condition change and/or becomes ill during dialysis, including knowing who will be contacted, who decides whether to stop dialysis, who documents the situation, under what circumstances dialysis may be terminated, and when treatment may be restarted or the next treatment scheduled. The record must reflect how the missed treatments will be addressed in order to prevent avoidable decline and other potential complications. If an HHD Patient wishes to decline treatment, Owner and Company social workers will coordinate services to address psychosocial concerns related to the HHD Patient's desire to discontinue dialysis treatments.

G. Company will communicate with Owner to monitor all ESRD-related supportive care of the HHD Patient outside of the dialysis treatment (monitoring weight, dietary/fluid intake, and other conditions related to fluid overload/depletion/infection/electrolyte imbalance postdialysis). Company and Owner will communicate and document responses related to: (i) timely medication administration; physician and treatment orders, laboratory values, and vital signs; (ii) advance directives and code status, specific directives about treatment choices, and any changes or need for further discussion with the HHD Patient/representative and practitioners; (iii) nutritional and fluid management, including documentation of weights, HHD Patient compliance with food/fluid restrictions or the provision of meals before, during or after dialysis, and monitoring intake and output measurements as ordered; (iv) dialysis treatment provided and the HHD Patient's response; (v) concerns related to the vascular access site; (vi) changes and/or a decline in condition unrelated to dialysis, such as patients who are at risk or who has a pressure ulcer; and (vii) the occurrence or risk of falls and any concerns related to transportation to and from the Treatment Den.

H. In accordance with CMS requirements, Company has developed dialysis-specific policies and procedures, which Company and Owner will work together during the Term to amend, update, and improve as necessary, that address the following: Identification all qualified staff permitted to provide HHD, under State licensing laws, who have received training provided by Company;

- (i) Documentation of training and competency requirements for individuals, both staff and caregivers, providing dialysis treatments;
- (ii) Procedures for the initiation, administration, and discontinuation of HHD treatments, type of monitoring required before, during, and after the treatments, including documentation requirements;
- (iii) Procedures for the methods of communication between the nursing home and the dialysis facility including how it will occur, with whom, and where the communication and responses will be documented;
- (iv) The development and implementation of interventions, based upon current standards of practice, including, but not limited to, documentation and monitoring of complications, pre- and post-dialysis weights, access sites, nutrition and hydration, lab tests, vital signs including blood pressure and medications;
- (v) Management of dialysis emergencies including procedures for medical complications, and for equipment and supplies necessary;
- (vi) The provision of medication on dialysis treatment days;

- (vii) Procedures for monitoring and documenting nutrition/hydration needs, including the provision of meals on days that dialysis treatments are provided;
- (viii) Assessing, observing and documenting care of access sites, as applicable, such as auscultation/palpation of the AV fistula (pulse, bruit and thrill) to assure adequate blood flow; significant changes in the extremity when compared to the opposite extremity (edema, pain, redness); Steal Syndrome (pain, numbness, discoloration, or cold to touch in the fingers or hand indicating inadequate arterial flow); skin integrity (waxy skin, ulcerations, drainage from incisions); bruising/hematoma; collateral vein distension (veins in access arm close to AV fistula becoming larger); complaints of pain or numbness; or evidence of infection at the surgical site, such as drainage, redness, tenderness at the incision site, fever;
- (ix) Safe and sanitary care and storage of dialysis equipment and supplies;
- (x) Responsibility for reporting adverse events, including who to report to, investigating the event, and correcting identified problems;
- (xi) Response and management of technical problems related to treatments, such as power outages, failure of HHD machines, clotting of the hemodialysis circuit, dialyzer blood leak, or line disconnection, and how and when to stop dialysis and/or seek help when there are significant issues; and
- (xii) Dialysis-specific infection control policies, including but not limited to transmission-based precautions including blood-borne precautions, placement/location (cohorting), staff/visitor personal protection equipment (PPE) requirements, indications for the use of gloves, masks, and hand hygiene; potential health care associated infections (HAI) including hepatitis B and tuberculosis; restrictions on visitors or roommates, if any, treatments; and handling, using, and disposing during of equipment/supplies, medications or other products in accordance with manufacturer's instructions and in accordance with all applicable Federal, State, and local laws and regulations. Company and Owner will not knowingly allow a HHD Patient who is hepatitis B + to dialyze in the Treatment Den.
- (xiii) Obtaining and reviewing dialysis facility monitoring for the dialysis water and dialysate quality, including total chlorine testing and at least quarterly testing of water and dialysate bacterial and endotoxin as applicable to the HHD equipment in use;
- (xiv) Types of furnishings allowed (such as recliners used during treatments) based on infection control standards and cleaning and sanitizing of furnishings that have the potential to become contaminated with blood and

blood products;

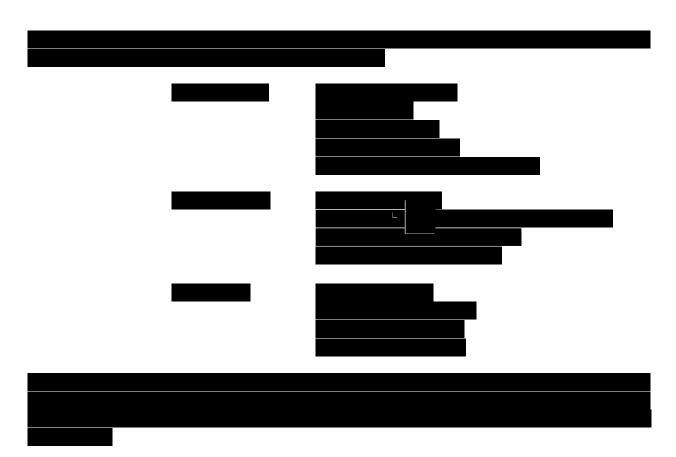
- (xv) Access to a clean sink for hand washing;
- (xvi) Disposal of dialysis by-products from the treatment;
- (xvii) Housekeeping and laundry policies for cleaning and sanitizing the locations where treatments are provided, including linen handling and waste disposal;
- (xviii) Vascular access and dressing changes; and
- (xix) Cleaning and disinfecting dialysis equipment, including procedures for spills and splashes of blood or effluent on furnishings, equipment, floors, and supplies.

The parties agree to review this Agreement annually to ensure proper and effective coordination between Company and Owner regarding HHD Patients.

6. <u>Term and Termination</u>.

A. This Agreement shall commence on the later of: (i) the date of last signature to this Agreement, or (ii) the date on which Company fully executes an agreement with a third party to provide medical director oversight of Services provided by Company Staff hereunder, or (iii) the date Owner provides fully functional Treatment Den and Storage Space, in compliance with the requirements of Sections 4.C and 4.M hereunder or (iv) the date on which the applicable governmental agency either issues a Certificate of Need ("CON") or a determination that no CON is needed for Services to be provided in accordance with Agreement (the "Effective Date"). All four conditions in the previous sentence must be satisfied in order for the Agreement to commence, and the Effective Date will be the first date on which all four conditions have been satisfied. This Agreement will continue in effect for a period of five (5) years and will automatically renew from year to year thereafter, unless otherwise terminated in accordance with the terms of this Agreement (collectively the "Term") or either party provides ninety (90) days' notice of intent to not renew.





23. <u>Compliance with Laws</u>. Each party agrees to operate in accordance with all applicable laws, rules, regulations and policies ("Laws") applicable to the Services contemplated to be performed by such party under this Agreement and, in the case of Owner, Laws that otherwise impact the medical care of the HHD Patients hereunder. Each party represents that it has all necessary licenses, permits and approvals necessary to perform its obligations hereunder.

24. <u>HIPAA</u>. The parties acknowledge that each is a Covered Entity, as defined in the Health Insurance Portability and Accountability Act ("HIPAA"). As such each party will, in performing its obligations under this Agreement, comply with all HIPAA laws and regulations, including but not limited to protecting the privacy and security of Protected Health Information, as defined in HIPAA.

25. <u>Elder Justice Act.</u> The parties will comply with the requirements of the Elder Justice Act Section 6703(b)(3) of the Patient Protection and Affordable Care Act and Section 1150B of the Social Security Act ("SSA"), including the reporting requirements set forth in Section1150(B)(b) of the SSA.

26. <u>Compliance Related Matters</u>. Owner and Company agree and certify that this Agreement is not intended to generate referrals for services or supplies for which payment may be made in whole or in part under any federally funded health care program, including but not limited to Medicare or Medicaid. Owner and Company will comply with all applicable statutes, rules, and regulations as promulgated by federal and state regulatory agencies or legislative authorities

having jurisdiction over the Parties.

27. <u>Excluded Provider</u>. Owner and Company hereby represents and warrants that each is not, and at no time has been, excluded from participation in any federally funded health care program, including but not limited to Medicare and Medicaid. Parties hereby agree to notify the other party immediately after it becomes actually aware of exclusion from any federally funded health care program, including but not limited to Medicare and Medicaid.

A. <u>Code of Conduct</u>. Company shall provide to Owner access to a copy of DaVita's Code of Conduct and relevant policies and procedures in either hard copy or electronic form (the "DaVita Policies and Procedures"), which are designed to ensure compliance with relevant Federal health care program requirements.

B. <u>Anti-Kickback Statute Compliance</u>. The Parties agree that: (i) neither Party shall violate the Anti-Kickback Statute with respect to the performance of this Agreement; (ii) the compensation provided under this Agreement has been determined in arm's-length bargaining and reflects fair market value in arm's-length transactions; and (iii) the compensation is not and has not been determined in a manner that takes into account the volume or value of any referrals or business otherwise generated for or with respect to or between the Parties for which payment may be made in whole or in part under Medicare, Medicaid, or any Federal or State health care program or under any other third party payor program.

C. <u>Screening Requirements</u>. Owner represents and warrants to Company that neither it nor any of its employees, contractors, subcontractors related to this Agreement: (i) are currently excluded from participation in an federal health care program, as defined under 42 U.S.C. § 1320a – 7(b); (ii) are currently excluded, debarred, suspended, or otherwise ineligible to participate in Federal procurement or non-procurement programs; or (iii) have been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a – 7(a), but have not yet been excluded, debarred, suspended, or otherwise declared ineligible. Owner agrees to notify Company within two (2) business days of learning of any such exclusion described above.

D. <u>Removal Requirement</u>. In the event of learning of such exclusion, as described in Section 27.C above, Company shall have the right to terminate this Agreement without further liability.

28. Access to Books and Records. Until the expiration of four (4) years after the furnishing of the Renal Dialysis Services pursuant to this Agreement, each party shall make available, upon written request of the Secretary of Health and Human Services or United States Comptroller General or any of their duly authorized representatives, access to review appropriate books and records relating to the performance of this Agreement to the extent required under Section 1861(v)(1)(I) of the Social Security Act, 42 U.S.C. Section 1395x(v)(1)(I). The access shall be provided in accordance with the provisions of 42 C.F.R. Part 420, Subpart D.

29. <u>Patient Choice</u>. Nothing in this Agreement is intended to restrict or limit a NF resident's choice to select a provider for his or her dialysis services. NF residents may receive traditional

HHD with a caregiver who is not Company or NF staff or may be transported to and from a facility of the resident's choosing to receive dialysis services.

30. <u>Equal Employment Opportunity/Affirmative Action</u>: If applicable to this contract, or any related subcontract, the equal employment opportunity clause for disabled workers (41 C.F.R. 60-741.5), the equal employment opportunity clause for women and minorities in Section 202 of Executive Order 11246 (41 C.F.R. 60-1.4), and the equal employment opportunity clause for protected veterans (41 C.F.R. 60-250.5 and 60-300.5), are hereby incorporated herein by reference.

31. <u>Counterparts; Approval by DaVita as to Form</u>. This Agreement may be executed in one or more counterparts, each of which is deemed to be an original, but all of which together constitute one and the same instrument. Facsimile or electronic signature are permitted, except where prohibited by law. The parties acknowledge and agree that this Agreement is legally binding upon the parties only upon full execution hereof by the parties and by DaVita as to the form hereof, however, DaVita's signature as to form will not be considered when calculating the Date of Last Signature as it is not a party hereto.

32. <u>Approval by State</u>. The parties acknowledge and agree that this Agreement will take effect and be legally binding upon the parties only on receipt of any and all necessary approvals regarding the Renal Dialysis Services hereunder from those state agencies having jurisdiction over the NF, if State approval is required.

[signature page follows]

IN WITNESS WHEREOF, the parties have executed this Agreement as of the Effective Date.

COMPANY:

Total Renal Care, Inc.

By: Dan Vialus By: Dan Vialus SB45DDD53E714CD... Name: Dan Viaches Title: General Manager, DaVita SNF Dialysis 4/27/2022

OWNER:

Prestige Care, Inc.

	DocuSigned by:
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Name:	Harold Delamarter, CEO
Title:	CEO
Date:	4/27/2022

APPROVED AS TO FORM:

DaVita Inc.

By:

Brittain Sexton

Name: Brittain Sexton

Title: Assistant General Counsel

<u>Exhibit A</u>

Treatment Rate Schedule

