

# Holland & Knight

1901 Sixth Avenue North, Suite 1400 | Birmingham, AL 35203 | T 205.226.5700 | F 205.214.8787  
Holland & Knight LLP | www.hklaw.com

Kristen A. Larremore  
(205) 226-5747  
kristen.larremore@hklaw.com

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STATE HEALTH PLANNING AND  
DEVELOPMENT AGENCY

October 22, 2024

**Via Electronic Filing (shpda.online@shpda.alabama.gov)**

Ms. Emily Marsal, Esq.  
Executive Director  
State Health Planning and Development Agency  
100 North Union Street, Suite 870  
Montgomery, Alabama 36104

RE: Request for Reviewability Determination  
DVA Renal Healthcare, Inc. d/b/a Red Mountain Home Training Dialysis  
18 ESRD Stations (ADPH Facility ID S3734)  
Home Hemodialysis in a Skilled Nursing Facility Dialysis Den

Dear Ms. Marsal:

The purpose of this letter is to request your determination, pursuant to Section 401-1-7-.02 of the Alabama Certificate of Need Program Rules & Regulations ("Regulations"), that the proposed provision of home dialysis services on site in a dialysis den at St. Martins in the Pines, 4941 Montevallo Road, Irondale, AL 35210 (ADPH Facility ID N3727) (the "St. Martin Facility") in Jefferson County, by DVA Renal Healthcare, Inc. d/b/a Red Mountain Home Training Dialysis ("DaVita Home") to residents of the St. Martin Facility does not require a Certificate of Need ("CON") from the State Health Planning and Development Agency.

The approximate project costs, including equipment, first year annual operating, and capital costs, associated with DaVita Home's proposed provision of on-site home dialysis services to residents of the St. Martin Facility in an onsite centralized dialysis den as described herein will not involve new costs to DaVita Home exceeding the following expenditure thresholds: (i) \$3,379,066.00 for major medical equipment; (ii) \$1,350,305.00 for new annual operating costs; and (iii) \$6,751,537.00 for capital expenditures.

DVA Renal Healthcare, Inc., referred to herein as DaVita Home, is a wholly-owned direct subsidiary of DaVita, Inc., a publicly traded entity.

Further, DaVita Home is a licensed end stage renal disease ("ESRD") facility located in Jefferson County with CON authorized home dialysis training stations, which are used to train patients to perform home hemodialysis and home peritoneal dialysis. DaVita Home is licensed and

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Medicare certified to provide home hemodialysis and home peritoneal dialysis training and support services. For the benefit of ESRD patients residing or staying in the St. Martin Facility, a 128-bed licensed skilled nursing facility ("SNF"), located at 4941 Montevallo Road, Irondale, AL 35205-4747, DaVita Home wishes to provide home hemodialysis services in the St. Martin Facility, pursuant to a written agreement between DaVita Home and the St. Martin Facility.

Residents of a SNF may receive chronic dialysis treatments through two options: (1) in center dialysis, and (2) home dialysis, in which the resident receives dialysis treatments in the SNF administered by the patient, a family member or friend, dialysis facility staff, or SNF personnel. Currently in Alabama, SNF residents requiring chronic dialysis treatments are typically transported to an off-site ESRD facility for in-center treatment. Transporting SNF residents off site for dialysis treatments is not ideal for the following reasons:

- (i) Risk of patient injury and discomfort due to the travel burden and particularly in the event of inclement weather;
- (ii) Expensive transportation costs and/or scheduling difficulties;
- (iii) Disruption to the care provided to the patient by SNF staff (rehabilitation, medications, meals, etc.);
- (iv) Potential breakdown in the coordination of care; and
  - For example, SNF onsite dialysis can help prevent unnecessary hospitalizations because SNF staff can intervene when issues not pertaining directly to dialysis arise while dialyzing (such as a spike in blood pressure) and can potentially prevent the need for emergency transport to a hospital that may be required if the patient is dialyzing in an ESRD facility.
- (v) Patient may be exposed to viruses and other illnesses during transport.

Upon confirmation of non-reviewability from the State Health Planning and Development Agency ("SHPDA") and approval from the Alabama Department of Public Health and the Centers for Medicare and Medicaid Services, DaVita Home will provide properly trained registered nurses, and patient care technicians to administer home hemodialysis treatments in the St. Martin Facility, solely to St. Martin Facility residents with chronic kidney failure. These St. Martin Facility residents will be home patients of the DaVita Home's home dialysis program. DaVita Home will not administer treatments at the St. Martin Facility to patients who are not residents of the St. Martin Facility.

DaVita home intends to use its proven dialysis den model that it has implemented at locations nationwide with six (6) traditional hemodialysis stations (such as the Fresenius 2008K2 or 2008T BlueStar machines) and AmeriWater reverse osmosis ("RO") system, or a comparable RO system, to provide the home hemodialysis services at the St. Martin Facility.<sup>1</sup> Traditional hemodialysis machines are the proven clinical standard for hemodialysis treatment. DaVita's experience with such equipment is that its use, and by allowing patients to continue to dialyze

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<sup>1</sup> See an overview of DaVita's SNF dialysis den model available here: <https://www.davita.com/partners/skilled-nursing-facilities>



three times per week (offers flexibility and can be used five times per week if so prescribed), results in optimal patient outcomes and allows for equivalent services to in-center care for the more fragile SNF patient population without the risks inherent in transport to an outside facility. Based upon DaVita's internal data, it has found that on-site SNF dialysis using traditional hemodialysis stations results in 15% fewer readmissions than if patients are treated off-site and 67% fewer hospitalizations as compared to patients dialyzing five times per week using the more traditional home dialysis model with equipment like NxStage. Additionally, according to a 2020 study in Hemodialysis International, SNF dialysis patients on a more frequent dialysis model using NxStage experienced the following challenges: (1) only 31% of patients actually received five treatments per week when they had stays in a nursing home longer than two weeks; (2) the patient population experienced a 62% overall hospitalization rate; and (3) 43% of admissions to the nursing home stayed less than two weeks with 68% ending in readmission.<sup>2</sup> Based upon DaVita's internal data, DaVita's SNF programs with traditional hemodialysis equipment results in less than three percent missed treatments due to patient non-compliance and 94% of patients are achieving dialysis adequacy goals. This is very important because, per a second study in Hemodialysis International, a single missed treatment is associated with a 1.4-fold greater risk of hospitalization, and a 2.2-fold greater risk of death in the subsequent 30 days.<sup>3</sup> Further, in the CMS Memo (defined below), CMS specifically states in the section of the memo titled "ESRD Policies and Procedures for Nursing Home Dialysis" on page 5 that "[t]he ESRD facility, in collaboration with the nursing home, should develop and implement protocols for the delivery of ESRD services, and to the extent possible, ensure that they are equivalent to the standards of care provided to dialysis patients receiving treatments in a dialysis facility." Accordingly, DaVita believes that its in-SNF dialysis den model utilizing traditional hemodialysis equipment is most closely aligned with this objective as specifically voiced by CMS and that it optimizes the patient care available to SNF residents in their home, thereby reducing the risks of adverse events to the maximum extent possible for this fragile SNF patient population with varying levels of clinical complexities.

As described, the ESRD equipment that DaVita Home seeks to use in the performance of the home hemodialysis treatment services at the St. Martin Facility, solely for residents of such facility in their home, will be the same hemodialysis equipment that is available to in-center ESRD facility hemodialysis patients. Guidelines for home dialysis treatment do not limit or prescribe the type of dialysis equipment that must be utilized for the home dialysis treatments, such that a typical in-center hemodialysis station can be used for such treatment in a patient's home. Providing home dialysis services to home dialysis patients who reside at the nursing home, which is considered the SNF resident's home for the purpose of home dialysis, is within the scope of DaVita Home's existing CON authority.

Further, home dialysis offers several general advantages when implemented within a SNF. This approach allows individuals with kidney failure to receive dialysis treatments in the comfort of their own environment while benefiting from the support and expertise of dialysis care

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<sup>2</sup> *Epidemiology of nursing home dialysis patients – A hidden population*, Eran Y. Bellin et al. 11 March 2021.

<sup>3</sup> See *In-center hemodialysis absenteeism: prevalence and association with outcomes*, Kathryn S. Grey et al. 24 May 2017.



technicians. Additionally, the integration of home dialysis services through a DaVita in-SNF dialysis den presents numerous benefits for both patients and healthcare providers, including the following:

- (i) Enhanced care coordination;
- (ii) Reduced readmissions and hospitalizations; and
- (iii) Better clinical outcomes.

The home dialysis den that DaVita Home seeks to implement at the St. Martin Facility is consistent with the standards and guidelines highlighted in the Center for Medicare & Medicaid's ("CMS") Center for Clinical Standards and Quality/Quality, Safety & Oversight Group memo addressed to State Survey Agency Directors, QSO-18-24-ESRD, as revised on March 22, 2023 ("CMS Memo").<sup>4</sup> See specifically CMS Memo page 7 "Nursing Home Dialysis in a Common Area." CMS explicitly acknowledges that ESRD facilities with an approved home training and support modality may provide home dialysis services to residents of a long term care facility, such as a SNF, and that such care is consistent with the Conditions for Coverage at 42 CFR Part 494 if the guidelines contained in such CMS Memo are followed. DaVita Home will also provide options for ESRD services at the St. Martin Facility either outside of the dialysis den utilizing the home dialysis equipment to the extent a resident needs services to be provided elsewhere or during specified times within the dialysis den permitting isolation for patients requiring isolation (such as if a patient has COVID). Additionally, DaVita Home and St. Martin Facility will honor a patient's choice to dialyze offsite if they do not want to be treated in the SNF as a home dialysis patient.

As required by CMS guidance regarding in-SNF dialysis set forth in the CMS Memo, DaVita Home will maintain direct responsibility for the dialysis-related care and services provided to the St. Martin Facility residents and will assure that such services are consistent with the ESRD Conditions for Coverage requirements set forth in 42 CFR 494.1 *et seq.* The St. Martin Facility and DaVita will enter into a written agreement reflecting responsibilities of each party, work together to ensure a safe and sanitary environment for the home dialysis treatments within the SNF's centralized dialysis den, ensure ongoing collaboration between the dialysis providers and the SNF staff, ensure adequate training for anyone that administers dialysis treatments, and appropriately monitor the dialysis patients' status before, during and after the treatments.

Upon confirmation of non-reviewability from SHPDA, St. Martin will pursue the ADPH Technical Services Unit plan review process to ensure that the dialysis space within the St. Martin Facility meets all applicable physical plant and Life Safety Code requirements. Following approval by the Technical Services Unit and receipt of the Certificate of Completion, St. Martin Facility and DaVita will coordinate with Health Provider Standards for review and approval of the

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<sup>4</sup> Available here: <https://www.cms.gov/medicare/provider-enrollment-and-certification/surveycertificationgeninfo/policy-and-memos-states/guidance-and-survey-process-reviewing-home-dialysis-services-nursing-home>

proposed arrangement. Prior to commencement of on-site home dialysis in the proposed dialysis den within the St. Martin Facility, facility staff will be trained on how to detect, report, and manage potential complications that may occur before, during or after a dialysis treatment.

In the event of an emergency at the proposed St. Martin Facility, DaVita Home will have in place emergency policies and procedures as required by 42 CFR § 494.62 including without limitation back-up plans that will be put in place and will be communicated to the nursing home for situations where a patient's routinely scheduled treatment is impacted due to reasons beyond their control. All DaVita Home staff involved in the on-site dialysis services at the St. Martin Facility will be trained on the emergency disconnect procedures. Further, the St. Martin Facility and DaVita Home will work together to ensure a safe and sanitary environment for the home dialysis treatments, including adherence to all emergency protocols.

Given that (i) DaVita has existing CON authority to offer home hemodialysis training and support (ii) the St. Martin Facility is considered the residents' "home" for purposes of home dialysis and (iii) the proposed on-site home dialysis den will offer hemodialysis services only to residents of the St. Martin Facility who will also be patients of the DaVita home dialysis program, we respectfully request your determination that DaVita is exempt from CON review and is not required to obtain a CON in order to provide the home dialysis services as described in this letter. We appreciate your consideration of this request, and welcome the opportunity to address any questions regarding this matter. A check for \$1,000.00 in payment for the applicable fee will be delivered to your office. Thank you very much.


Best regards,

  
Kristen A. Larremore



Affirmation of Requesting Party:

The undersigned, being first duly sworn, hereby makes oath or affirms that she/he, as the Group Regional Operations Director overseeing DVA Renal Healthcare, Inc. d/b/a Red Mountain Home Training Dialysis, has knowledge of the facts in the attached Reviewability Determination Request, and to the best of her/his information, knowledge and belief, such facts are true and correct.

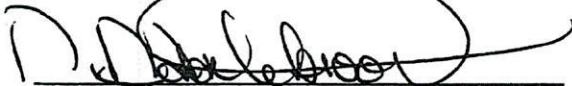


Name: Douglas Lavin

Title: Group Regional Operations Director

(SEAL)

SUBSCRIBED AND SWORN to before me this 21<sup>st</sup> day of October, 2024.



Notary Public

My Commission Expires: 9/3/28

