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October 20, 2023

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

RV2024-001
RECEIVED

Oct 20 2023

STATE HEALTH PLANNING AND
DEVELOPMENT AGENCY

**RE: Request for Reviewability Determination
Fresenius Medical Care Birmingham Home, LLC d/b/a Fresenius Medical Care
Birmingham Home (ADPH Facility ID S3733)
Home Hemodialysis in a Skilled Nursing Facility**

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 at Cavalier Healthcare of Trussville (ADPH Facility ID N3755) (the “Cavalier Facility”) in Trussville, Jefferson County, by Fresenius Medical Care Birmingham Home, LLC d/b/a Fresenius Medical Care Birmingham Home (“Fresenius”) to residents of the Cavalier Facility does not require a Certificate of Need (“CON”) from the State Health Planning and Development Agency. In order to assist with this determination, we offer the following information:

Fresenius is a licensed end stage renal disease (“ESRD”) facility located in Jefferson County with CON authorized home dialysis training stations, which are used interchangeably to train patients to perform home hemodialysis and home peritoneal dialysis. Fresenius is licensed and 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 Cavalier Facility, a licensed skilled nursing facility (“SNF”), sometimes referred to as a nursing home or long term care facility, located at 119 Watterson Pkwy, Trussville, AL 35173, Fresenius wishes to provide home hemodialysis services in the Cavalier Facility, pursuant to a written agreement between Fresenius and Cavalier.

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 inclement weather;
- (ii) Expensive transportation costs;
- (iii) Disruption to the care provided to the patient by SNF staff (rehabilitation, medications, meals, etc.);
- (iv) In-center dialysis patients are largely limited to receiving dialysis treatment only three times per week;
- (v) Potential breakdown in the coordination of care; and
- (vi) Patient may be exposed to viruses and other illnesses during transport.

Upon confirmation of nonreviewability 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, Fresenius will provide properly trained registered nurses, and patient care technicians to administer home hemodialysis treatments in the Cavalier Facility to Cavalier Facility residents with chronic kidney failure using the NxStage HHD system and PureFlow SL ultrapure water and dialysate preparation system. These Cavalier Facility residents will be home patients of the Fresenius home dialysis program. Fresenius will not administer treatments at the Cavalier Facility to patients who are not residents of the Cavalier Facility. The equipment used to perform the hemodialysis treatment is the same portable hemodialysis equipment that is currently used by Fresenius home hemodialysis patients in their homes. Providing home dialysis services to home dialysis patients at the nursing home, which is considered the SNF resident’s home for the purpose of home dialysis, is within the scope of Fresenius’s existing CON authority.¹

Home dialysis offers several 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 technicians. The integration of home dialysis in a SNF presents numerous benefits for both patients and healthcare providers, including the following:

- (i) eliminate the need for patient to be transported to a dialysis center for dialysis treatments;
- (ii) minimizes risk of exposure to viruses and illnesses from outside facilities;
- (iii) minimizes risk of slip, fall or other medical incident after treatment or during transport back to SNF;
- (iv) better able to maintain patient’s rehabilitation, medical appointment, meal and activity schedules; and
- (v) increased access to flexible dialysis options, including more frequent hemodialysis.

Importantly, research has found that more frequent hemodialysis is associated with improved clinical outcomes in patients in SNFs.² Residents receiving more frequent hemodialysis

¹ Fresenius has CON authority for home dialysis under various CONs, including CON 2953-ESRD, issued in June 2021 to approve the addition of five dialysis home training stations at the Fresenius facility.

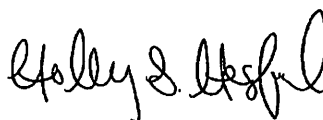
² Weinhandl E, Hocking K, Markovich S, Vavrinchik S, Collins A. *Increased Hemodialysis Frequency is Associated with Improved Clinical Outcomes Among Patients in Skilled Nursing Facilities*. Abstract Presented at ASN 2018.

in a SNF setting experience 34% lower risk of mortality, 23% lower risk of cardiovascular hospitalization, and 17% lower risk of hospitalizing (excluding infection) as compared to conventional hemodialysis (three times per week).

As required by CMS guidance set forth in “Guidance and Survey Process for Reviewing Home Dialysis Services in a Nursing Home”, QSO-18-24-ESRD, revised in March 2023, Fresenius will maintain direct responsibility for the dialysis-related care and services provided to the Cavalier 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 Cavalier Facility and Fresenius will work together to ensure a safe and sanitary environment for the home dialysis treatments. Upon confirmation of nonreviewability from SHPDA, Cavalier will pursue the ADPH Technical Services Unit plan review process to ensure that the dialysis space within the Cavalier 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, Cavalier Facility and Fresenius will coordinate with Health Provider Standards for review and approval of the proposed arrangement. Prior to commencement of on-site home dialysis, Cavalier Facility staff will be trained on how to detect, report, and manage potential complications that may occur before, during or after a dialysis treatment.

Given that (i) Fresenius has existing CON authority to offer home hemodialysis training and support (ii) the Cavalier Facility is considered the residents’ “home” for purposes of home dialysis and (iii) the proposed on-site home dialysis will be offered only to residents of the Cavalier Facility who will also be patients of the Fresenius home dialysis program, we respectfully request your determination that Fresenius 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,

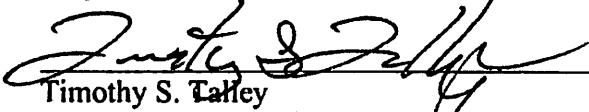


Holly S. Hosford

Based on a retrospective study of 3,619 patients comparing those that received >4.5 hemodialysis treatments per week to those receiving <4.5 treatment per week in the SNF setting between 2011 and 2015.

Affirmation of Requesting Party:

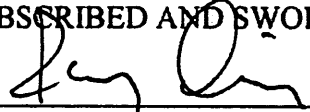
The undersigned, being first duly sworn, hereby makes oath or affirms that he, as the Regional Director of Operations of Fresenius Kidney Care overseeing Fresenius Medical Care Birmingham Home, has knowledge of the facts in the attached Reviewability Determination Request, and to the best of his information, knowledge and belief, such facts are true and correct.



Timothy S. Talley
Regional Director of Operations, Fresenius Kidney Care

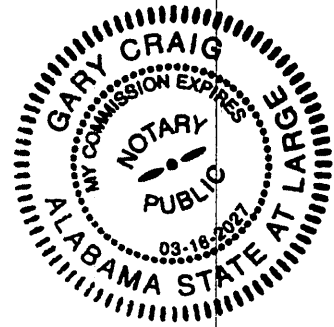
(SEAL)

SUBSCRIBED AND SWORN to before me this 19th day of October, 2017 ^{2023 (G.C.)}



Notary Public
My commission expires: 03-16-2027

Alabama
Limestone County



Holly S. Hosford
hhosford@bradley.com
205.521.8376

Bradley

November 3, 2023

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: RV2024-001
Fresenius Medical Care Birmingham Home, LLC d/b/a Fresenius Medical Care
Birmingham Home
Response to Request for Additional Information

Dear Ms. Marsal:

This letter is written in response to the Agency's October 25, 2023 letter requesting that we provide the Agency with additional information related to the Reviewability Determination Request submitted on behalf of Fresenius Medical Care Birmingham Home, LLC ("FMC Birmingham Home").

The Agency's letter requests that FMC Birmingham Home provide approximate project costs, including equipment, first year annual operating, and capital costs, associated with the proposed provision of on-site home dialysis services to residents of Cavalier Healthcare of Trussville, a licensed skilled nursing facility. The proposal will not involve new costs to FMC Birmingham Home exceeding the following expenditure thresholds: (i) \$3,322,582.00 for major medical equipment; (ii) \$1,327,734.00 for new annual operating costs; and (iii) \$6,638,679.00 for capital expenditures.

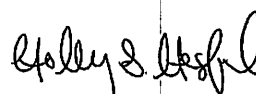
The Agency's letter also requests that FMC Birmingham Home provide the Agency with planned emergency procedures in place on behalf of the Reviewability request. In the event an emergency occurs, the caregiver will disconnect the patient receiving dialysis in accordance with FMC Birmingham Home's emergency disconnect procedures and contact 911. All staff involved in the on-site home dialysis services at Cavalier Healthcare of Trussville will be trained on the emergency disconnect procedures. As stated in the Request for Reviewability Determination, The Cavalier Facility and FMC Birmingham Home will work together to ensure a safe and sanitary environment for the home dialysis treatments, including adherence to emergency protocols.

Finally, the Agency's letter requests that FMC Birmingham provide a disclosure of financial interests in the entity requesting the reviewability determination. Fresenius Medical Care Birmingham Home, LLC is a joint venture between Bio-Medical Applications of Alabama, Inc. and Central Alabama Home Dialysis Ventures, L.L.C. Bio-Medical Applications of Alabama, Inc. is an indirect wholly-owned subsidiary of Fresenius Medical Care Holdings, Inc. Fresenius Medical Care Holdings, Inc. is an indirect wholly-owned subsidiary of Fresenius Medical Care AG & Co. KGaA and the corporate parent of Fresenius entities providing dialysis services in North America.

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We appreciate your assistance with this Reviewability Determination Request. As always, please do not hesitate to contact me if you have any questions or if we can address any further issues relating to this project.

Best regards,

A handwritten signature in black ink, appearing to read "Holly Hosford". The signature is written in a cursive style with a large, looped initial "H".

Holly Hosford