

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: January 25, 2023

Findings Date: January 25, 2023

Project Analyst: Ena Lightbourne

Co-Signer: Gloria C. Hale

Project ID #: L-12269-22

Facility: Wilson Home Dialysis

FID #: 200032

County: Wilson

Applicant(s): FMS ENA Home, LLC

Project: Develop one dialysis station to be used exclusively for home hemodialysis training and support services, a change of scope for CON Project ID# L-11836-20

REVIEW CRITERIA

G.S. 131E-183(a): The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

NC

FMS ENA Home, LLC (hereinafter referred to as “the applicant” or “ENA Home”), proposes to develop one dialysis station at Wilson Home Dialysis, dedicated exclusively to home hemodialysis (HH) training, a change of scope for Project ID# L-11836-20 (develop a new dialysis facility dedicated to providing home peritoneal dialysis (PD) training and support services). Upon completion of this project and Project ID# L-11836-20, Wilson Home Dialysis will be certified for HH and PD training and support services.

Conclusion

The Agency reviewed the:

- Application

- Exhibits to the application
- Written comments
- Information publicly available during the review and used by the Agency

Bases on that review, the Agency concludes that the application is not conforming to the criterion because there is no county need determination in the 2022 State Medical Facilities Plan (SMFP) for any additional dialysis stations. Table 9B on page 138 of the 2022 SMFP shows there is a surplus of 16 dialysis stations in Wilson County. Adding an additional dialysis station would increase the surplus of dialysis stations. Home hemodialysis stations are certified dialysis stations and are included in the ESRD planning inventory.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to develop one dialysis station at Wilson Home Dialysis dedicated exclusively to HH; a change of scope for Project ID# L-11836-20 (develop a new dialysis facility dedicated to providing PD training and support services).

Patient Origin

On page 115, the 2022 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located.*” Thus, the service area for this facility consists of Wilson County. Facilities may also serve residents of counties not included in their service area.

Wilson Home Dialysis is currently under development, therefore, there is no historical payor mix to report. The following table illustrates projected patient origin for the second full fiscal year.

Wilson Home Dialysis Projected Patient Origin				
County	2nd Full FY CY 2025			
	# of HH Patients	% of Total	# of PD Patients	% of Total
Wilson	8.4	100.0%	26.7	100.0%
Total	8.4	100.0%	26.7	100.0%

Source: Section C, page 26

In Section C, pages 26-33 and Section Q, pages 94-101, the applicant provides the assumptions and methodology used to project its patient origin.

Home Hemodialysis

- In Project ID# L-11836-20, the applicant was approved to develop Wilson Home Dialysis offering PD training and support services in Wilson County. BMA, co-parent of the applicant and Eastern Nephrology Associates (ENA), are committed to increasing the home therapy penetration rate in Wilson County. Physicians from ENA serve chronic kidney disease patients and serve as a referral source for dialysis facilities. BMA facilities currently serve some dialysis patients in Wilson County.
- Chowan Home Dialysis, a facility owned by the applicant, was certified April 2022 (Project ID# R-12268-22) and has served 11 PD patients in the first four months of operation which will exceed 12.6 PD patients by the end of the first operating year as projected in the original application. The applicant states that this demonstrates the commitment to increase home therapy penetration in the Chowan County service area, which will be the same commitment in Wilson County.
- The applicant identified patients in other counties that ENA serves from eastern North Carolina who could potentially choose home therapy services at Wilson Home Dialysis. The applicant assumes that patients prefer to be served in their home county. The applicant does not project growth for these patients since home therapy patients do not have to travel to a center three times a week after training.
- The applicant cites data from the CMS Dialysis Compare website to illustrate the number of facilities in Wilson County offering home therapy. According to the data, there are only two dialysis facilities in Wilson County offering HH and/or PD. The applicant assumes that the proposal will offer another option for Wilson County residents.
- The applicant projects growth using the Five-Year Average Annual Change Rate (AACR) of 3.5% for Wilson County, as published in the 2022 SMFP.
- The applicant identified three HH patients who are residents of Wilson County receiving services at the Greenville Dialysis facility in Pitt County. There are eight Wilson County PD patients that will eventually require a transplant or voluntarily change to HH. The applicant assumes that three of these patients will be required convert to HH in the near future. Additionally, the applicant identified two HH patients residing in Nash County expressing their interest in transferring their care to Wilson Home Dialysis.
- Based on the Executive Order to advance kidney health nationally, the applicant assumes that more patients will be referred for home dialysis.
- ENA Home has a history of achieving a home penetration greater than 45% and assumes that ENA Home can achieve a home penetration of at least 25% based on the number of counties across the state historically achieving a home penetration that exceeds 25%. The applicant identified the home penetration in a county similar to Wilson County. The applicant compares the following counties based on a similar ESRD patient population.

County	Home Penetration	ESRD Census
Buncombe	26.8%	284
Wilson	23.2%	314

Source: Section C, page 30

- Despite having an ESRD patient population of 10.6% smaller than Wilson County, Buncombe County home penetration is 15.5% larger than Wilson County. The applicant states that this suggests that more Wilson County patients can dialyze at home.
- A physician at ENA supports the proposal and intends to refer patients for home therapies to the facility.
- The applicant relied on information from Edgecombe Home Dialysis (Edgecombe) to project future patient population at Wilson Home Dialysis, based on the following factors:
 - Edgecombe offers HH and PD training and support services. Wilson Home Dialysis is proposing to offer the same services.
 - Edgecombe relies on nephrology physicians of ENA for patient referrals and admissions as Wilson Home Dialysis is proposed to do.
 - Wilson Home Dialysis is proposed to have a medical director from the same practice.
 - Edgecombe is located approximately 33 miles away from Wilson Home Dialysis.
 - Edgecombe and Wilson are contiguous counties and share similar population data, as illustrated below:

	Wilson	Edgecombe
Women	52.3%	53.6%
Men	47.7%	46.4%
Population aged 65+	19.0%	21.1%
Population aged < 65	81.0%	78.9%
Black or African American	40.5%	57.5%
White, not Hispanic or Latino	46.0%	35.6%
American Indian/Alaska Native	0.8%	0.8%
Asian	1.2%	0.4%
Native Hawaiian and other Pacific Islander	0.2%	0.2%
Under age 65 with disability	10.3%	11.8%
Under age 65 without health insurance	15.1%	11.4%
Persons in poverty	21.2%	24.1%

Source: Section C, page 31

The applicant cites data from the 2020 SMFP through the proposed 2023 SMFP, to illustrate Edgecombe County patient population growth, particularly among HH patients.

Edgecombe County ESRD Census					
SMFP	2020	2021	2022	Proposed 2023	CAGR
Date of Data	12/31/2018	12/31/2019	12/31/2020	12/31/2021	4.14%
ESRD	247	247	264	279	

Source: Section C, page 32

Edgecombe County Home Hemodialysis Census					
Data Source	2020 SMFP	2021 SMFP	2022 SMFP	Proposed 2023 SMFP	CAGR
Data Period	12/31/2018	12/31/2019	12/31/2020	12/31/2021	
# Home Hemodialysis Patients	3	4	4	8	38.67%
% Increase		33.3%		100.0%	

Source: Section C, page 32

- The project is projected to be certified as of December 31, 2023. The applicant projects the first operating year of the project will be January 1, 2024 - December 31, 2024, and the second operating year will be January 1, 2025 - December 31, 2025.

Home Peritoneal Dialysis

In Project ID# L-11836-20, the applicant projected that at the beginning of the first operating year, Wilson Home dialysis will serve 23 PD patients and at the end of the same operating year, the facility will serve 26.7 PD patients. The Agency determined the applicant had demonstrated its projected utilization was based on reasonable and adequately supported assumptions. The applicant proposes no changes in the current application which would change the projected utilization from the previous project, or which would otherwise affect the Agency’s determination in that project.

The applicant’s assumptions are reasonable and adequately supported based on the following:

- The applicant adequately demonstrates the growth of HH and PD patients in Wilson County and at other facilities serving home therapy patients.
- The applicant projects growth of Wilson County patients using the Five-Year AACR for Wilson County, as published in the 2022 SMFP.
- The applicant’s proposal supports the Executive Order to improve kidney health.

Analysis of Need

In Section C, pages 35-37, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- Developing an additional dialysis station dedicated to HH will enhance access to care as the need for home therapy grows.
- The proposed project and Project ID# L-11836-20 will focus exclusively on HH and PD which will allow residents of Wilson County and surrounding areas access to HH and PD training and support services.
- Failure to receive dialysis care will lead to the patient’s demise.

The information is reasonable and adequately supported based on the following:

- The growth in the home therapy patient population in the applicant’s similar facilities.
- The applicant’s proposal will improve access to HH services for Wilson County patients currently served in other counties.

Projected Utilization

In Section C, page 34, and Section Q, page 102, the applicant provides projected utilization, as illustrated in the following table.

Wilson Home Dialysis	HH Patients
Begin with six Wilson County patients expected to transfer and convert to HH when the station is certified on December 31, 2023.	6.0
Add the two Nash County patients expected to transfer to the facility when the station is certified on December 31, 2023. This is the projected ending census for Interim Year One.	$6.0 + 2.0 = 8.0$
Project the Wilson County patient census forward for 12 months to December 31, 2024, using the Wilson County Five-Year AACR.	$6.0 \times 1.035 = 6.2$
Add the two patients from other counties. This is the projected ending census for Operating Year One.	$6.2 + 2.0 = 8.2$
Project the Chowan County patient census forward for 12 months to December 31, 2025, using the Wilson County Five-Year AACR.	$6.2 \times 1.035 = 6.4$
Add the two patients from other counties. This is the projected ending census for Operating Year Two.	$6.4 + 2.0 = 8.4$

Wilson Home Dialysis	PD
Begin with the 23 Wilson County patients expected to begin treatment at the facility as proposed in the original application.	23.0
Project the Wilson County patient census forward for 12 months as proposed in the original application. This is the projected ending census for Operating Year One.	25.0
Project the Wilson County patient census forward for 12 months as proposed in the original application. This is the projected ending census for Operating Year Two.	26.7

In Section C, page 34 and Section Q, page 101, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The applicant begins with the six patients residing in Wilson County, three who are HH patients and three who are PD patients that will transfer to HH care when the station is certified on December 31, 2023.
- The applicant begins with 23 PD patients expected to begin treatment at Wilson Home Dialysis, as proposed in Project ID# L-11836-20.
- The applicant assumes that two HH patients residing in Nash County will transfer their care to Wilson Home Dialysis when the station is certified on December 31, 2023.
- The applicant projects growth of the Wilson County HH patient census using the Wilson County Five-Year AACR of 3.5%, as published in the 2022 SMFP.
- The project is projected to be certified as of December 31, 2023. The first operating year of the project will be January 1, 2024 - December 31, 2024, and the second operating year will be January 1, 2025 - December 31, 2025.

The applicant projects to serve the following number of patients upon completion of this project and Project ID# L-11836-20.

	Operating Year 1	Operating Year 2
Home Hemodialysis	8.2	8.4
Peritoneal Dialysis	25.0	26.7

Source: Section C. page 34

Projected utilization is reasonable and adequately supported based on the following:

- The applicant projects growth of HH patients using the Five-Year AACR for Wilson County, as published in the 2022 SMFP.
- The applicant projects utilization based on the growth of home therapy in Wilson County.

Access to Medically Underserved Groups

In Section C. page 39, the applicant states:

“Fresenius Medical Care and its related facilities in North Carolina have historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an underserved person. For example, Medicare (includes Medicare Advantage treatments) represented 77.82% of North Carolina dialysis treatments in Fresenius related facilities in FY 2021; Medicaid treatments represented an additional 6.87% of treatments in our facilities for FY 2021.”

The applicant provides the estimated percentage for each medically underserved group during the second full fiscal year, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low-income persons	20.59%
Racial and ethnic minorities	91.18%
Women	44.12%
Persons with Disabilities	8.82%
Persons 65 and older	32.35%
Medicare beneficiaries	26.47%
Medicaid recipients	20.59%

Source: Section C, page 39

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The applicant relied on the Edgecombe Home Dialysis facility as a model for its patient population projections, based on the facility’s similarity in services offered, referral and admission source, and its location to the proposed Wilson Home Dialysis.
- The applicant is an established provider of dialysis services across North Carolina currently providing services to underserved groups.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will

be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

NC

The applicant proposes to develop one dialysis station dedicated exclusively to HH; a change of scope for Project ID# L-11836-20 (develop a new dialysis facility dedicated to providing PD training and support services).

In Section E, page 50, the applicant states that there were no other alternatives considered and any other alternative would not support the former President's Executive Order on Advancing American Kidney Health. On page 50, the applicant states:

“At the present time, there are only two dialysis facilities operating in Wilson County that offer home therapies and only one of them offers home hemodialysis at the time this application was prepared and submitted. The applicant believes that offering home hemodialysis services to patients of Wilson County and surrounding counties would bring those services closer to the patient's residence...”

However, the applicant does not adequately demonstrate that the alternative proposed in this application is the most effective alternative to meet the need because the application is not conforming to all other statutory and regulatory review criteria. An application that cannot be approved cannot be an effective alternative to meet the need.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

Based on that review, the Agency concludes that the application is not conforming to this criterion for the reason stated above. Therefore, the application is denied.

- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to develop one dialysis station dedicated exclusively to HH; a change of scope for Project ID# L-11836-20 (develop a new dialysis facility dedicated to providing PD training and support services).

Capital and Working Capital Costs

In Section Q, page 104, the applicant projects the total capital cost of the project, as shown in the table below.

Non-Medical Equipment	\$750
Furniture	\$3,000
Total	\$3,750

In Section Q, page 105, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on what is needed to operate the facility, such as patient chairs and the water treatment system.

Availability of Funds

In Section F, page 51, the applicant states that the capital cost will be funded, as shown in the table below.

Type	FMS ENA Home, LLC	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$3,750	\$3,750
Bonds	\$0	\$0
Other	\$0	\$0
Total Financing	\$3,750	\$3,750

* OE = Owner's Equity

The applicant is proposing a change of scope to Project ID# L-11836-20 by developing one dialysis station to be used exclusively for HH training and support services. In Section F, page 56, the applicant states that HH training and support services will increase the proposed working capital cost demonstrated in Project ID# L-11836-20, as illustrated in the table below.

New total estimated start-up costs	\$168,691
New total estimated initial operating costs during initial operating period	\$732,851
New total working capital	\$901,542
Previously approved total working capital	\$744,970
Difference	\$156,572

On pages 56-57, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are reasonable based on the following methodology:

- The estimated start-up expense represents four weeks of the operating expense less salary and benefits expenses.
- The estimated annual start-up expense is calculated by dividing the operating expenses less the salary and benefits expenses by 13.

Exhibit F-2 contains a letter dated September 15, 2022, from the Senior Vice-President and Treasurer of Fresenius Medical Holdings, Inc., majority owner of FMS ENA Home, LLC, stating their commitment to fund the capital and working capital needs of the project through accumulative reserves. The letter states the Fresenius Medical Holdings’ 2021 consolidated balance sheet reflected \$939 million in cash and over \$27.2 billion in total assets to fund the project.

The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project based on the information provided in Section F and Exhibit F-2 of the application.

Financial Feasibility

The applicant provided pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Form F.2, the applicant projects that revenues will exceed operating expenses in the first two full fiscal years following completion of the project, as shown in the table below.

Wilson Home Dialysis	1st Full FY	2nd Full FY
	CY2024	CY 2025
Total Treatments	4,774	5,057
Total Gross Revenues (Charges)	\$30,031,598	\$31,813,360
Total Net Revenue	\$1,895,655	\$2,009,009
Average Net Revenue per Treatment	\$397	\$397
Total Operating Expenses (Costs)	\$1,465,703	\$1,518,140
Average Operating Expense per Treatment	\$307	\$300
Net Income	\$429,952	\$490,869

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q, page 108. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant provides reasonable assumptions in determining revenue and operating expenses in preparation of Form F.2, F.3 and F.4.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal for all the reasons described above.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

NC

The applicant proposes to develop one dialysis station dedicated exclusively to HH; a change of scope for Project ID# L-11836-20 (develop a new dialysis facility dedicated to providing PD training and support services).

On page 115, the 2022 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located.*” Thus, the service area for this facility consists of Wilson County. Facilities may also serve residents of counties not included in their service area.

The table below lists the existing and approved facilities, certified stations, and utilization of dialysis facilities in Wilson County as of December 31, 2021. According to 2021 ESRD Data

Collection Forms submitted to the Agency, there were four kidney disease treatment centers providing dialysis services and one approved but not yet operational in Wilson County. Only one facility was serving home patients.

Facility Name	Certified Stations as of 12/31/2021	# IC Patients as of 12/31/2021	Utilization by Percent as of 12/31/2021	Patients Per Station Per Week
Forest Hill Dialysis	35	86	61.25%	2.45
Kenly Dialysis	10	20	50.00%	2.00
Sharpsburg Dialysis	10	9	22.50%	0.90
Wilson Dialysis	44	119	67.50%	2.70
Total	99	234		

Source: 2021 ESRD Data Collection Forms

In Section G, page 60, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Wilson County. The applicant states:

“Wilson Home Dialysis seeks the opportunity to provide critical dialysis care and treatment to the patients of the area who are currently leaving the county for dialysis treatment and who are receiving dialysis treatment at other Fresenius related facilities. The applicant being able to offer home hemodialysis in addition to peritoneal dialysis at the facility would enhance access to services and provide an alternate provider of services...”

However, the applicant does not adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved services in the service area because the proposal would result in an additional dialysis station for which there is no county need determination. Thus, the addition of a dialysis station in Wilson County would increase an existing surplus of dialysis stations in Wilson County. An alternative method or policy for developing new dialysis stations that would be used exclusively for home hemodialysis training, and that would not require a need determination in the SMFP would need to be developed and approved by the State Health Coordinating Council.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is not conforming to this criterion for all the reasons described above.

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

The applicant proposes to develop one dialysis station dedicated exclusively to HH; a change of scope for Project ID# L-11836-20 (develop a new dialysis facility dedicated to providing PD training and support services).

In Section H, page 116, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Projected FTE Staff	
	1 st Full FY CY 2024	2 nd Full FY CY 2025
Administrator (FMC Clinic Manager)	1.00	1.00
Home Training Nurse	3.00	3.00
Dietician	0.25	0.25
Social Worker	0.25	0.25
Maintenance	0.10	0.10
Administrative/Business Office	0.50	0.50
Other: FMC Director of Operations	0.10	0.10
Other: Chief Technician	0.05	0.05
Other: FMC In-Service	0.05	0.05
TOTAL	5.30	5.30

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.4. In Section H, pages 62-63, the applicant describes the methods to be used to recruit or fill new positions and its existing training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant is proposing to offer a wide range of personnel benefits and competitive salaries to attract qualified staff.
- In response to the pandemic’s impact on staffing, parent company Fresenius Medical Care, has implemented initiatives such as, sign-on and retention bonuses, increased starting salaries and intensified recruiting efforts.

- New employees are required to complete a 10-week training program that includes safety precautions in addition to clinical training.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

The applicant proposes to develop one dialysis station dedicated exclusively to HH; a change of scope for Project ID# L-11836-20 (develop a new dialysis facility dedicated to providing PD training and support services).

Ancillary and Support Services

In Section I, page 64, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 64-69, the applicant explains how each ancillary and support service is or will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available.

Coordination

In Section I, page 69, the applicant describes its existing and proposed relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on following:

- The applicant's established relationships with other physicians and hospitals in the area, which include Eastern Nephrology Associates Access Center, where ESRD patients may receive care.
- The applicant has agreements for lab services, hospital affiliation and transplant.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by

other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

The applicant does not propose to construct any new space or renovate any existing space. Therefore, Criterion (12) is not applicable to this review.

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and ... persons [with disabilities], which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

(a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

NA

In Section L, page 76, the applicant states that Wilson Home Dialysis is currently under development, therefore, there is no historical payor mix to report for the previous full fiscal year.

(b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and persons with disabilities to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 79, the applicant states:

“The facility is not obligated under any applicable federal regulations to provide uncompensated care, community service, or access by minorities and persons with disabilities.”

In Section L, page 79, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application

- Exhibits to the application
- Written comments

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section L, page 79, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Wilson Home Dialysis Projected Payor Mix 2nd Full FY, CY 2025				
Payor Source	HH		PD	
	# of Patients	% of Total	# of Patients	% of Total
Self-Pay	0.0	0.00%	0.0	0.00%
Insurance*	1.7	20.67%	6.0	22.62%
Medicare*	6.7	79.33%	17.3	64.74%
Medicaid*	0.0	0.00%	1.1	4.08%
Other Misc. including VA	0.0	0.00%	2.3	8.56%
Total	8.4	100.00%	26.7	100.00%

*Including any managed care plans.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 79.33% of total services will be provided to HH Medicare patients and 64.74% to PD Medicare patients, and 4.08% to PD Medicaid patients. On page 80, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- The applicant calculated payor mix based upon treatment volumes as opposed to the number of patients. The applicant considered the possible change in payor source during the fiscal year.
- Payor mix projections are based on Edgecombe Home Dialysis' historical facility performance.
- The applicant states that Medicaid HH patients will have access to the facility.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section L, pages 81-82, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

The applicant proposes to develop one dialysis station dedicated exclusively to HH; a change of scope for Project ID# L-11836-20 (develop a new dialysis facility dedicated to providing PD training and support services).

In Section M, page 83, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-1. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following:

- Fresenius Medical Care facilities have a history of allowing health-related education and training programs visit the facility to observe the operation of the unit while patients receive treatment.

- The applicant provides a copy of a letter sent to Eastern Carolina University, encouraging the school to include Wilson Home Dialysis facility in their clinical rotations for nursing students.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

NC

The applicant proposes to develop one dialysis station dedicated exclusively to HH; a change of scope for Project ID# L-11836-20 (develop a new dialysis facility dedicated to providing PD training and support services).

The table below lists the existing and approved facilities, certified stations, and utilization of dialysis facilities in Wilson County as of December 31, 2021. According to 2021 ESRD Data Collection Forms submitted to the Agency, there were four kidney disease treatment centers providing dialysis services and one approved but not yet operational in Wilson County. Only one facility was serving home patients.

Facility Name	Certified Stations as of 12/31/2021	# IC Patients as of 12/31/2021	Utilization by Percent as of 12/31/2021	Patients Per Station Per Week
Forest Hill Dialysis	35	86	61.25%	2.45
Kenly Dialysis	10	20	50.00%	2.00
Sharpsburg Dialysis	10	9	22.50%	0.90
Wilson Dialysis	44	119	67.50%	2.70
Total	99	234		

Source: 2021 ESRD Data Collection Forms

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 84, the applicant states:

“The SMFP reports there are four operational dialysis facilities in Wilson County, all operated by DaVita Dialysis. Wilson Home Dialysis is a joint venture operation by Fresenius Medical Care and Eastern Nephrology Associates, PA... Wilson Home Dialysis seeks the opportunity to provide critical dialysis care and treatment to the patients of the area. Approval of this application will also provide residents of Wilson County with enhanced access to an alternate provider to address the nationwide interest and support for expansion of home dialysis services.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 85, the applicant states:

“Approval of this application will ensure continued access to care for the patients; this proposal will ensure continued convenient, affordable access to care for the growing number of home dialysis patients.”

See also Sections C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 85, the applicant states:

“Quality of care is always in the forefront at Fresenius Medical Care related facilities. Quality care is not negotiable. Fresenius Medical Care, parent organization for this facility, expects every facility to provide high quality care to every patient at every treatment.”

See also Section O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 85, the applicant states:

“Fresenius related facilities in North Carolina have historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for

being an underserved person. Low income and medically underinsured persons will continue to have access to all services provided by Fresenius related facilities.”

See also Section L of the application and any exhibits.

However, the applicant does not adequately describe the expected effects of the proposed services on competition in the service area and adequately demonstrate the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant does not adequately demonstrate that:

- 1) The proposal is cost effective because the applicant did not adequately demonstrate that the proposal would not result in an unnecessary duplication of existing and approved health services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is not conforming to this criterion based on the reason described above.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Section Q, pages 118-122, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 125 of this type of facility located in North Carolina.

In Section O, page 90, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents resulting in immediate jeopardy had not occurred in any of these facilities. After reviewing and considering information provided by the applicant, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

G.S. 131E-183 (b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and

may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

NA

The applicant proposes to develop a new kidney disease treatment center dedicated to providing home training and support services for home hemodialysis and peritoneal dialysis patients. The Criteria and Standards for End Stage Renal Disease Services, promulgated in 10A NCAC 14C .2200, are not applicable to this review due to a declaratory ruling issued by the Agency on October 10, 2018, which exempts the Criteria and Standards from applying to proposals to develop or expand facilities exclusively serving home hemodialysis and peritoneal dialysis patients.