

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 16, 2020

Findings Date: June 16, 2020

Project Analyst: Tanya M. Saporito

Team Leader: Fatimah Wilson

Project ID #: Q-11835-20

Facility: Hertford Home Dialysis

FID #: 200030

County: Hertford

Applicant: FMS ENA Home, LLC

Project: Develop a new dialysis facility in Ahoskie to provide home peritoneal dialysis training and support services

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Agency 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.

NA

FMS ENA Home, LLC (the applicant), proposes to develop a new dialysis facility in Ahoskie to provide home peritoneal dialysis (PD) training and support services. The facility would be known as Hertford Home Dialysis and would be located at 1201 West First Street in Ahoskie. The applicant, FMS ENA Home, LLC, is a joint venture between Bio-Medical Applications of North Carolina, Inc. (BMA) and Eastern Nephrology Associates. Bio-Medical Applications of North Carolina, Inc. is a wholly owned subsidiary of Fresenius Medical Care Holdings, Inc. (FMC or Fresenius). The facility will not provide either in-center (IC) dialysis nor home hemodialysis (HH). At project completion, Hertford Home Dialysis will be a standalone kidney disease treatment center offering training and support exclusively for PD patients dialyzing at home.

The applicant does not propose to:

- develop any beds or services for which there is a need determination in the 2020 State Medical Facilities Plan (SMFP);
- acquire any medical equipment for which there is a need determination in the 2020 SMFP;
- offer a new institutional health service for which there are any policies in the 2020 SMFP.

Therefore, Criterion (1) is not applicable to this review.

- (2) Repealed effective July 1, 1987.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, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to develop a new dialysis facility in Ahoskie to provide home peritoneal dialysis training and support services.

Patient Origin

On page 113, the 2020 SMFP defines the service area for dialysis stations as, “*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” Hertford Home Dialysis is proposed to be located in Hertford County. Thus, the service area for this facility is Hertford County. Facilities may also serve residents of counties not included in their service area.

The applicant projects patient origin on page 17, as illustrated in the following table:

COUNTY	SECOND FULL FY OF OPERATION FOLLOWING PROJECT COMPLETION 1/1/2023 - 12/31/2023	
	# OF PD PATIENTS	% OF TOTAL
Hertford	9.96	100.00%
Total	9.96	100.00%

Source: Section C.3, page 17.

In Section C, pages 18-25, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 25-26, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed peritoneal dialysis services. The applicant explains that patients with End Stage Renal Disease (ESRD) require dialysis treatments on a regular basis, usually three times weekly, to maintain life. Typically, the dialysis treatments are based on a Monday-Wednesday-Friday or Tuesday-Thursday-Saturday shift in the in-center dialysis facilities.

The applicant states home PD trained patients require the same consistent dialysis treatment regimen; the difference is that a PD patient is able to receive these treatments at home rather than a dialysis facility. The applicant's demonstration of need is further summarized as follows:

- The applicant states this application is focused on developing a new, free-standing kidney disease treatment center that focuses on training patients to perform peritoneal dialysis at home or at another venue, using the dialysis facility as a location for follow-up care, consultation, and additional training.
- The applicant states that scheduling dialysis treatments during scheduled times in a facility may not be convenient for the patient, which leads to compliance issues and high missed treatment rates.
- The applicant states that approval of this application would enable Hertford County dialysis patients who prefer home dialysis training the opportunity to dialyze at home in a convenient setting at times that are convenient to the patient.

In Section A, page 7, the applicant references an Executive Order on Advancing American Kidney Health issued on July 10, 2019 by President Trump which, in part, encourages greater use of home dialysis by patients. The Executive Order states, "*Greater rates of home dialysis and transplantation will improve quality of life and care for patients who require dialysis....*"

The applicant notes on page 7 and pages 18-19 of the application that since July 2019 Fresenius dialysis facilities have seen a tremendous shift in referral trends with facilities experiencing a significantly larger number of referrals for home dialysis.

In Section C, page 19, the applicant states that peritoneal dialysis patients tend to be the majority of those patients who choose to and are able to dialyze at home. The applicant states that 100% of the home patients residing in Hertford County utilized home peritoneal dialysis; none of the home patients in Hertford County utilized home hemodialysis. Therefore, the applicant concludes that it is reasonable to project more Hertford County patients will elect to use home peritoneal dialysis.

On page 26, the applicant states it selected the site in Ahsoskie primarily for patient convenience, because "*Ahsoskie is the largest city in Hertford County, and is therefore likely to be central to more of the patient population.*"

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

- There is continued Federal focus and emphasis on home dialysis training pursuant to the Presidential Executive Order of July 10, 2019.
- The applicant states its facilities have experienced an increase in home dialysis patients since the Presidential Executive Order of July 10, 2019.
- The applicant’s stated increase in referral trends for home dialysis treatment experienced by Fresenius Medical Care both in North Carolina and nationwide since July 2019.

Projected Utilization

In both Section C, pages 17 and 24-25, and Section Q, the applicant projects utilization, as illustrated in the following table:

COUNTY	FIRST FULL FY OF OPERATION FOLLOWING PROJECT COMPLETION 1/1/2022 TO 12/31/2022		SECOND FULL FY OF OPERATION FOLLOWING PROJECT COMPLETION 1/1/2023 TO 12/31/2023	
	# OF PD PATIENTS	% OF TOTAL	# OF PD PATIENTS	% OF TOTAL
Hertford	9.38	100.00%	9.96	100.00%
Total	9.38	100.00%	9.96	100.00%

In both Sections C and Q, the applicant provides the assumptions and methodology used to project utilization, as summarized below:

- The applicant states it does not currently have a dialysis facility in Hertford County, but states that Fresenius Medical Care, the applicant’s co-parent and a majority interest holder in FMS ENA Home, LLC is serving “some” dialysis patients from Hertford County. According to Table 9A, page 131 of the 2020 SMFP, BMA was serving 13 Hertford County dialysis patients as of December 31, 2018.
- The applicant states that Eastern Nephrology Associates (ENA), the minority interest in FMS ENA Home, LLC currently serves many patients who have End Stage Renal Disease as well as advanced chronic kidney disease who reside in Hertford County. ENA also admits ESRD patients to seven Fresenius-related facilities across eastern North Carolina.
- The applicant assumes Hertford County ESRD patients would prefer to receive dialysis care in their home county. The 2020 SMFP reports that of the 93 ESRD patients in Hertford County, 20.4% (19) were home peritoneal dialysis patients.
- The applicant notes that the majority of home dialysis patients in North Carolina and Hertford County tend to be PD patients, citing Table 9A in the 2020 SMFP. That table shows North Carolina had a total of 18,732 dialysis patients as of December 31, 2018.

Of those, 2,380 were home patients, and 1,899 [80% of home patients] were PD patients. That same table shows that all of the home patients in Hertford County as of December 31, 2018 were PD patients. Thus, the applicant concludes that PD dialysis is the preferred method of home dialysis training and support for Hertford County patients. The applicant states that in the second half on 2019, following the Presidential Executive Order, its facilities experienced “a significantly larger number of referrals for home dialysis.”

- The applicant assumes the ESRD patient population in Hertford County can achieve a home penetration rate of 25%, particularly since the home patient population in Hertford County was 20% as of December 31, 2018.
- The applicant points out that many of the North Carolina counties with a home dialysis patient population of 20% or higher either have a small overall ESRD patient population or have no dialysis facility in the county. The applicant specifically compares Haywood and Hertford counties, which have somewhat similarly sized dialysis patient populations, as shown in the following table:

Comparison of ESRD Home Penetration Rates

COUNTY	HOME PENETRATION	ESRD CENSUS
Haywood	26.30%	76
Hertford	20.40%	93

*Source: table on page 20 of the application.

The applicant notes that Haywood County has a smaller overall ESRD patient population but more home patients; thus, the applicant states more patients can dialyze at home.

- The applicant assumes continued referral from ENA physicians, and thus the number of patients choosing home dialysis will continue to increase. The applicant was approved in 2017 to develop Edgecombe Home Dialysis and states the number of home patients served by Edgecombe Home Dialysis nearly doubled since the facility opened. See the following table, from page 21 of the application:

Edgecombe County Historical ESRD Census

SDR*	JULY 2016	JULY 2017	JULY 2018	JULY 2019
DATE OF DATA	12/31/15	12/31/16	12/31/17	12/31/18
ESRD Patients	214	230	224	247
Home Patients	16	17	27	36
% Home Patients	7.5%	7.4%	12.0%	14.6%

*The Agency formerly published ESRD need methodologies in a separate publication, the Semiannual Dialysis Report (SDR). That information is now published in chapter 9 of each year’s SMFP.

The applicant notes that the information shows the total ESRD patient population increased by 5.05%, while the home dialysis patient population increased by 32.80% from December 31, 2015 to December 31, 2018.

- The applicant states the home dialysis patient population of Hertford County will have similar results.
- The applicant assumes the ratio of home PD patients will remain constant. The applicant does not propose to offer home hemodialysis training or support, nor in-center dialysis. The applicant proposes to offer only PD dialysis training and support in Hertford County.
- The applicant assumes the home patient penetration rate in Hertford County, currently at 20%, will increase to 25% of all dialysis patients in the county by December 31, 2021.
- The applicant begins its calculations with the Hertford County ESRD patient population as of December 31, 2018. At that time, there were 93 ESRD patients, 19 of whom (20.4%) were PD patients.
- Of those 19 home patients, three were being served by a dialysis related facility. The applicant states that number increased to four as of December 31, 2019 as reported in the ESRD Data Collection Form submitted to the Agency in February 2020.
- The applicant projects the dialysis patient population forward by the Hertford County Five Year AACR of 3.0% for each of the two operating years following project completion and assumes an incremental increase in the number of home patient penetration.
- Operating Year 1 is January 1, 2022 to December 31, 2022 (CY 2022).
- Operating Year 2 is January 1, 2023 to December 31, 2023 (CY 2023).
- For OY1 (CY 2022) and OY2 (CY 2023) the applicant assumes that 75% of Hertford County residents utilizing PD treatment will receive their training and support at Hertford Home Dialysis based on physician letters of support.

In Section C, pages 22-24 and in Section Q, the applicant provides the calculations used to arrive at the projected PD patient census for OY1 and OY2 as summarized in the table below.

Begin with the ESRD population of Hertford County residents as of December 31, 2018 IC Patients: 74 PD Patients: 19 Total Patients: 93 Total % of Home Patients: 20.4%	93
Project Hertford County patients forward one year to December 31, 2019, using the Hertford County Five Year AACR of 3.0%.	$93 \times 1.03 = 95.8$
Increase the PD patient percentage to 21.95%, representing an incremental change to 25%.	$95.8 \times 0.2195 = 21.03$ PD patients
Project Hertford County patients forward one year to December 31, 2020, using the Hertford County Five Year AACR of 3.0%.	$95.8 \times 1.03 = 98.7$
Increase the PD patient percentage to 23.47%, representing an incremental change to 25%.	$98.7 \times 0.2347 = 23.16$ PD patients
Project Hertford County patients forward one year to December 31, 2021, using the Hertford County Five Year AACR of 3.0%.	$98.7 \times 1.03 = 101.6$
Increase the PD patient percentage to 25%, representing an incremental change to 25% by December 31, 2021.	$101.6 \times 0.25 = 25.41$ PD patients
Determine the number of new home patients by subtracting 19 home patients (December 31, 2018) from the projected 25.4	$25.41 - 19 = 6.41$
Assume 75% of those new home patients will transfer their care to Hertford Home Dialysis as of December 31, 2021. This is the projected starting census for Hertford Home Dialysis.	$6.41 \times 0.75 = 4.80$ 4.8 new PD patients + 4 existing PD patients = 8.80
Project Hertford County patients forward one year to December 31, 2022, using the Hertford County Five Year AACR of 3.0%.	$101.6 \times 1.03 = 104.7$
Maintain the 25% home percentage.	$104.7 \times 0.25 = 26.17$ PD patients
Determine the number of new home patients by subtracting 19 home patients (December 31, 2018) from the projected 26.17.	$26.17 - 19 = 7.17$
Assume 75% of those new home patients will transfer their care to Hertford Home Dialysis. This is the ending PD patient census for Hertford Home Dialysis for Operating Year 1	$7.17 \times 0.75 = 5.38$ $5.38 + 4 = 9.38$ PD patients
Project Hertford County patients forward one year to December 31, 2023, using the Hertford County Five Year AACR of 3.0%	$104.7 \times 1.03 = 107.8$
Maintain the 25% home percentage.	$107.8 \times 0.25 = 26.96$ PD patients
Determine the number of new home patients by subtracting 19 home patients (December 31, 2018) from the projected 29.65.	$29.65 - 19 = 10.65$
Assume 75% of those new home patients will transfer their care to Hertford Home Dialysis. This is the ending PD patient census for Hertford Home Dialysis for Operating Year 2	$10.65 \times 0.75 = 7.99$ $7.99 + 4 = 11.99$ PD patients

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

- The applicant projects future utilization based on historical utilization of all ESRD patients (IC and PD) who are residents of Hertford County using reasonable growth projections.
- Future growth of all Hertford County PD ESRD patients is based on the Five-Year AACR for Hertford County.

- The applicant’s projection that home patient penetration of Chowan County will increase to 25% by December 31, 2021 is reasonable given that: home patient penetration of Hertford County was already at 20.4% as of December 31, 2018. An increase to 25% at the end of 2021 only represents an incremental increase of 2.25% per year for three years. Additionally, the Presidential Executive Order on Advancing American Kidney Health issued on July 10, 2019 has already affected an increase in Fresenius home patient referrals.
- The applicant provides letters of support from Eastern Nephrology Associates.
- The applicant only projects that it would serve 75% of the Hertford County residents who utilize PD for treatment based on PD patients they are currently serving at other Fresenius-related facilities and based on referrals from ENA nephrologists.

Access

In Section C.7, page 27, the applicant states,

“Fresenius operates more than 100 dialysis facilities across North Carolina. Each of these facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.

It is corporate policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.

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.”

In Section L, page 53, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

PAYOR CATEGORY	PD SERVICES AS A % OF TOTAL
Self-Pay	2.44%
Insurance*	39.37%
Medicare*	44.42%
Medicaid*	3.69%
Medicare/Commercial	8.25%
Misc. Incl. VA	1.83%
Total	100.00%

*Includes managed care plans.

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information which was 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 the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

- (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, handicapped persons, 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.

CA

The applicant proposes to develop a new dialysis facility in Ahoskie to provide exclusively home peritoneal dialysis training and support services.

In Section E, page 34, the applicant states that there were no alternatives other than to apply or not apply, in order to better serve the Hertford County ESRD PD patient population that chooses to dialyze at home.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need based on the following reasons:

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative to serve the PD patient population in Hertford County.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. FMS ENA Home, LLC shall materially comply with all representations made in the certificate of need application.**
 - 2. FMS ENA Home, LLC shall establish a freestanding home dialysis training and support program exclusively for peritoneal dialysis patients, with no home hemodialysis stations.**
 - 3. FMS ENA Home, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (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 a new dialysis facility in Ahoskie to provide home peritoneal dialysis training and support services.

Capital and Working Capital Costs

In Section Q, Form F.1a, page 81, the applicant projects the total capital cost of the project, as shown in the table below.

Site Costs	\$0
Construction Costs	\$675,383
Miscellaneous Costs	\$195,163
Total	\$870,546

In Section Q, the applicant provides the assumptions used to project the capital cost.

In Section F, page 36, the applicant projects that start-up costs will be \$117,187 and initial operating expenses will be \$280,977 for a total working capital of \$398,164. On pages 37-38, the applicant provides the assumptions and methodology used to project the working capital needs of the project.

Availability of Funds

In Section F, page 35, the applicant states that the capital cost will be funded, as shown in the table below:

Sources of Capital Cost Financing

TYPE	FMS ENA HOME, LLC	TOTAL
Loans	\$	\$
Accumulated reserves or OE *	\$870,546	\$ 870,546
Bonds	\$	\$
Other (Specify)	\$	\$
Total Financing	\$870,546	\$870,546

* OE = Owner's Equity

In Section F, page 38, the applicant states that the working capital needs of the project will be funded, as shown in the table below:

Sources of Working Capital Financing

TYPE	FMS ENA HOME, LLC	TOTAL
Loans	\$	\$
Accumulated reserves or OE *	\$398,164	\$398,164
Bonds	\$	\$
Other (Specify)	\$	\$
Total Financing	\$398,164	\$398,164

Exhibit F-2 contains a letter dated January 15, 2020 from the Senior Vice President and Treasurer of Fresenius Medical Care Holdings, Inc. (FMCH), the majority owner of FMS ENA Home, LLC, authorizing and committing cash reserves in the amount of \$870,546 for the capital costs of the project and any startup costs and initial operating costs as many be needed for the project. The letter states that FMCH currently has \$1.8 billion in cash and cash equivalents and \$20 billion in total assets.

Financial Feasibility

The applicant provided pro forma financial statements for the first three 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 operating years of the project, as shown in the table below.

	1st Full Fiscal Year	2nd Full Fiscal Year
Total Treatments	1,345.4	1,431.2
Total Gross Revenues (Charges)	\$8,463,635	\$9,003,847
Total Net Revenue	\$703,967	\$748,900
Average Net Revenue per Treatment	\$523	\$523
Total Operating Expenses (Costs)	\$561,954	\$580,289
Average Operating Expense per Treatment	\$417	\$405
Net Income	\$142,013	\$168,611

Numbers may not sum due to rounding by Project Analyst

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal.
- 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 costs and charges.

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

The applicant proposes to develop a new dialysis facility in Ahoskie to provide home peritoneal dialysis training and support services.

On page 113, the 2020 SMFP defines the service area for dialysis stations as: “the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.” Hertford Home Dialysis is proposed to be in Hertford County. Thus, the service area for this facility is Hertford County. Facilities may also serve residents of counties not included in their service area.

According to Table 9B: *Inventory of Dialysis Stations and Calculation of Utilization Rates* on page 157 of the 2020 SMFP, there are two existing dialysis facilities in Hertford County, both operated by DaVita, as shown in the following table:

DIALYSIS FACILITY	CERTIFIED STATIONS	# PD PATIENTS	# HHD PATIENTS	# OF IC PATIENTS	% IN-CTR. UTILIZATION
Ahoskie Dialysis	26	10	0	65	62.50%
Roanoke-Chowan Dialysis	10	0	0	14	35.00%
Total	36	10	0	79	

Source: Table 9B of the 2020 SMFP, page 157 and Table 9A of the 2020 SMFP, page 131

The applicant proposes to develop a new dialysis treatment center to provide home PD training and support to patients currently and projected to be served by nephrologists who are currently treating and referring BMA patients.

In Section G, page 41, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Chowan County. The applicant states:

“This project does not involve dialysis stations.

The project does involve development of a new kidney disease treatment center. The new center will serve exclusively home peritoneal dialysis patients. Home training and support services for peritoneal dialysis patients does not utilize dialysis stations.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based on the following reasons:

- The proposal would not develop new in-center dialysis stations in Hertford County.
- The applicant adequately demonstrates that the proposed new dialysis facility which will only provide home peritoneal dialysis training and support services is needed in addition to the existing dialysis facilities in the service area.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information which was 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 based on the reasons stated 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

In Section Q, Form H, page 92, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services for the first two operating years (OY), as illustrated in the following table.

POSITION	PROJECTED FTE STAFF	PROJECTED FTE STAFF
	1 ST FULL OY (CY 2022)	2 ND FULL OY (CY 2023)
Administrator (FMC Clinic Mgr)	0.75	0.75
Home Training Nurse	0.50	0.50
Dietician	0.10	0.10
Social Worker	0.10	0.10
Maintenance	0.10	0.10
Admin/Business Office	0.20	0.20
Other: FMC Dir. Operations	0.10	0.10
Other: In-Service	0.50	0.50
Other: Chief Tech	0.05	0.05
TOTAL	2.40	2.40

The assumptions and methodology used by the applicant to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.4, which is found in Section Q. In Section H.2 and H.3, page 42, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs. In Section H.4, page 43, the applicant identifies the proposed medical director. In Exhibit H-4, the applicant provides a letter from the proposed medical director indicating an interest in serving as medical director for the proposed services.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

In Section I, page 44, the applicant states that the following ancillary and support services are necessary for the proposed services:

ANCILLARY AND SUPPORT SERVICES	
SERVICE	PROVIDER
Self-care training	On site
Home training	Referral to Greenville Dialysis Center
HH	
PD	
Accessible follow-up program	On Site
Psychological counseling	Referral to Vidant Health
Isolation – hepatitis	On site
Nutritional counseling	On site
Social Work services	On site
Acute dialysis in an acute care setting	Referral to Vidant Health in Greenville
Emergency care	Provided by staff until ambulance arrival
Blood bank services	Referral to Vidant Health
Diagnostic and evaluation services	Referral to Vidant Health
X-ray services	Referral to Vidant Health
Laboratory services	On site
Pediatric nephrology	Referral to Vidant Health
Vascular surgery	Referral to Vidant Health
Transplantation services	Referral to Vidant Health
Vocational Rehabilitation & Counseling	Vidant Outpatient Rehabilitation, Vidant Chowan Hospital
Transportation	Roanoke Medical Transport; Chowan County Social Services

On pages 44-45, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibits I-1.1, I-1.2, I-1.3 and I-1.4.

In Section I, pages 44-45 the applicant describes its efforts to develop relationships with other local health care and social service providers and provides supporting documentation in Exhibit H-4.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

- (9) Based on that review, the Agency concludes that the application is conforming to this criterion. 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.

C

In Section K, page 47, the applicant states that the project involves renovating 3,400 square feet of existing space. Line drawings are provided in Exhibit K-2.

On pages 47-48, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal.

On page 48, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

On pages 48-49, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

On pages 49-50, and in Exhibit K-4, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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 handicapped persons, 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

Neither the applicant nor any related entities own, operates or manages an existing health service facility located in the service area. Therefore, Criterion (13a) is not applicable to this review.

- (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 handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

NA

Neither the applicant nor any related entities own, operates or manages an existing health service facility located in the service area. Therefore, Criterion (13b) is not applicable to this review.

- (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 53, 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.

PAYOR CATEGORY	PD SERVICES AS A % OF TOTAL
Self-Pay	2.44%
Insurance*	39.37%
Medicare*	44.42%
Medicaid*	3.69%
Other: Medicare/Commercial	8.25%
Other: Misc. Incl. VA	1.83%
Total	100.00%

*Includes any managed care plans.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 2.44% of total services will be provided to self-pay patients, 52.67% to Medicare patients and 3.69% to Medicaid patients.

On page 53, 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 historical payor mix of actual treatment volumes of Edgcombe Home Dialysis, an existing freestanding facility for peritoneal dialysis home training and support services, which is located approximately 49 miles from the proposed facility.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to 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, page 54, 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

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

In Section M, page 55, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M-2.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

- (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.

C

The applicant proposes to develop a new dialysis facility in Ahoskie to provide home peritoneal dialysis training and support services.

On page 113, the 2020 SMFP defines the service area for dialysis stations as, “*the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” Hertford Home Dialysis is proposed to be in Hertford County. Thus, the service area for this facility is Hertford County. Facilities may also serve residents of counties not included in their service area.

According to Table 9B: *Inventory of Dialysis Stations and Calculation of Utilization Rates* on page 157 of the 2020 SMFP, there are two existing dialysis facilities in Hertford County, both operated by DaVita, as shown in the following table:

Hertford County Dialysis Facilities Utilization as of 12/31/2018

DIALYSIS FACILITY	CERTIFIED STATIONS	# PD PATIENTS	# HHD PATIENTS	# OF IC PATIENTS	% IN-CTR. UTILIZATION
Ahoskie Dialysis	26	10	0	65	62.50%
Roanoke-Chowan Dialysis	10	0	0	14	35.00%
Total	36	10	0	79	

Source: Table 9B of the 2020 SMFP, page 157 and Table 9A of the 2020 SMFP, page 131

The applicant proposes to develop a new dialysis facility to provide home PD training and support services to patients who are currently and projected to be served by nephrologists who are currently treating and referring BMA patients.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 56, the applicant states:

“The applicant does not expect this proposal to have any effect on the competitive climate in Hertford County. The applicant does not project to serve dialysis patients currently being served by another provider. The applicant has not forecast any patients to change dialysis providers.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 57, the applicant states:

“This is a proposal to develop a new peritoneal dialysis training facility to be located in Ahoskie, Hertford County. There is currently only one provider offering home training. Approval of this application will allow another provider to offer high quality services. Fresenius Medical Care (co-parent to the applicant) and physicians of Eastern Nephrology are serving a number of dialysis patients residing in the area. Approval of this application will allow the applicant to develop a new kidney disease treatment center and continue serving patients who reside in the area, in a more convenient location. ... This is an immediate and significantly positive impact to the patients of the area.”

Regarding the impact of the proposal on quality, in Section N, page 57, the applicant states:

“Quality of care is in the forefront at Fresenius related facilities. Quality care is not negotiable. ... Our organizational mission statement captures this sentiment very well:

‘We deliver superior care that improves that quality of life of every patient, every day, setting the standard by which others in the healthcare industry are judged.’”

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 57, the applicant states:

“It is corporate policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.

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.”

Considering all the information in the application, the applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on:

- Cost-effectiveness (see Sections C, F, N and Q of the application and any exhibits)
- Quality (see Sections C, N and O of the application and any exhibits)
- Access to medically underserved groups (see Sections C, L and N of the application and any exhibits)

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information which was 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 based on the reasons stated 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 Form A Facilities, 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 125 dialysis facilities owned, operated, or managed by the applicant or a related entity located in North Carolina.

In Section O.2, page 62, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to quality of care that resulted in a finding of “*Immediate Jeopardy*” occurred in any of these facilities. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all Fresenius facilities, the applicant provides 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.
- (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 dialysis facility in Ahoskie, Hertford County to provide home peritoneal dialysis training and support services. 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 HH and PD patients.