

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: April 24, 2020

Findings Date: April 24, 2020

Project Analyst: Gregory F. Yakaboski

Team Leader: Fatimah Wilson

Project ID #: R-11834-20

Facility: Chowan Home Dialysis

FID #: 200027

County: Chowan

Applicant: FMS ENA Home, LLC

Project: Develop a new dialysis facility in Edenton 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 Edenton to provide home peritoneal dialysis (PD) training and support services. The facility would be known as Chowan Home Dialysis to be located at 125 Claire Drive in Edenton. 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, Chowan 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- (2) Repealed effective July 1, 1987.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 Edenton 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.*” Chowan Home Dialysis is proposed to be in Chowan County. Thus, the service area for this facility is Chowan County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates projected patient origin.

County	Second Full FY of Operation following Project Completion 1/1/2023 to 12/31/2023	
	# of PD Patients	% of Total
Chowan	14.31	100.00%
Total	14.31	100.00%

Source: Section C.3, page 17.

In Section C, pages 18-24, 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 17-26, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant explains the typical three day per week schedule for in-center patients to receive dialysis and states the failure to receive dialysis services will lead to patient death. On page 25, the applicant states:

“Home dialysis patients – PD and home hemodialysis – require the same regular dialysis treatment regimen. ... The need that this population has for the proposed services is a function of the individual patient need for dialysis care and treatment.

...

Dialysis schedules at times which are not convenient for the patient will adversely affect patient compliance and lead to higher missed treatment rates. Home dialysis affords the patient maximum flexibility with scheduling treatment at times which are convenient, and in the patient residence. The patient has total control of the treatment.

Dialysis in a setting which is not convenient for the patient, similarly leads to patient compliance issues and higher missed treatment rates.

Approval of this application will allow the applicant to develop a free standing home training facility focused exclusively on the home peritoneal dialysis patient. This will enhance patient training opportunities and ultimately will allow Chowan Home Dialysis to enable more patients to dialyze at home in a convenient setting, at times which are convenient for 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 based on the Executive Order it is *“reasonable to project that more patients will be referred for home dialysis”*, which has been the experience of Fresenius both specifically in North Carolina as well as across the country. Since July 2019 the applicant states that within Fresenius dialysis facilities there has been a tremendous shift in referral trends with Fresenius Medical Care 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 home patients citing Table 9A of the 2020 SMFP as showing that as of December 2018 the breakdown in home dialysis treatment showed 1,899 home peritoneal dialysis patients as compared to 481 home hemodialysis patients. Specifically, for patients residing in Chowan County, of the seven home patients six utilized home peritoneal dialysis and only one utilized home hemodialysis. Therefore, the applicant concludes that it is reasonable to project more patients will elect to use home peritoneal dialysis.

On page 26, the applicant states,

The applicant has selected the site in Edenton primarily for patient convenience. ... the nearest home training program is greater than 30 miles from Edenton. Brining dialysis ... closer to the patient residence is a service to the patient.

At the present time there is not a home training program available within Chowan County. Consequently, patients desiring to dialyze at home must travel significant distances for home training. Once the patient begins home dialysis, the patient still must return to the dialysis clinic monthly for lab draws and clinical visits.”

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

- Federal focus and emphasis on home dialysis pursuant to the Presidential Executive Order of July 10, 2019.
- Chowan County currently not having a facility offering home training and support.
- The 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 26, and Section Q, the applicant provides projected 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
Chowan	12.58	100.00%	14.31	100.00%
Total	12.58	100.00%	14.31	100.00%

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

- Operating Year 1 is January 1, 2022 to December 31, 2022 (CY2022).
- Operating Year 2 is January 1, 2023 to December 31, 2023 (CY2023).
- The applicant begins its utilization projections by using the Chowan County residents ESRD patient population as of December 31, 2018 which was 50 total patients: 43 IC patients; 6 PD patients and 1 HH patient. See Table 9A: Dialysis Data by County of Patient Origin-December 2018 Data, page 123, of the 2020 SMFP.

- The applicant projects the ESRD population of patients who reside in Chowan County will grow at the Five Year Average Annual Change Rate (AACR) for Chowan County, 13.8%, as stated in Table 9C: ESRD Dialysis Station Need Determinations by Planning Area, page 166, of the 2020 SMFP.
- The percent of Chowan County residents receiving dialysis by home treatment (either PD or HH) as opposed to IC dialysis is 14.0% as of December 31, 2018. [7 PD or HH patients/ 50 total Chowan County resident ESRD patients = 0.14 or 14%]
- As of December 31, 2018, Chowan County PD patients comprised 85.7% of the patients receiving home treatment [6 PD patients/ 7 total home treatment = 0.8571 or 85.7%]
- The applicant projects that the percentage of Chowan County residents who receive dialysis by home treatment as compared to the overall number of Chowan County residents who receive dialysis (IC, PD or HH), 14.0% as of December 31, 2018, will increase by 3.67% for a total of 17.67% in CY2019; 3.67% for a total of 21.34% in CY2020; 3.66% for a total of 25.00% in CY2021 and remain stable at 25.00% for both CY2022 and CY2023. The 3.67% increase is based on the projection that home patient penetration of Chowan County will increase to a rate of 25% by December 31, 2021 and that the increase will occur incrementally.
- For CY2019 to CY2023 the applicant projects that 80% of the total Chowan County residents receiving home dialysis treatment will be PD patients and 20% will be HH patients.
- For OY1 (CY2022) and OY2 (CY2023) the applicant assumes that 75% of Chowan County residents utilizing PD treatment will be dialyzing with Chowan Home Dialysis based on physician letters of support.

In Section C, pages 23-24 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 Chowan County residents as of December 31, 2018 IC Patients: 43 PD Patients: 6 HH Patients: 1 Total Patients: 50	50
Project Chowan County patients forward one year to December 31, 2019, using the Chowan County Five Year AACR of 13.8%.	$50 \times 1.138 = 56.9$ Total Dialysis Patients
Project the number of home patients of Chowan County residents as of December 31, 2019 by increasing the percent of home patients from 14% to 17.67% (by 3.67%)	$56.9 \times .1767 = 10.1$ Total Home Patients PD patients: $10.1 \times .80 = 8.08$ HH patients: $10.1 \times .20 = 2.01$
Project Chowan County patients forward one year to December 31, 2020, using the Chowan County Five Year AACR of 13.8%.	$56.9 \times 1.138 = 64.8$ Total Dialysis Patients
Project the number of home patients of Chowan County residents as of December 31, 2020 by increasing the percent of home patients from 17.67% to 21.34% (by 3.67%)	$64.8 \times .2134 = 13.8$ Total Home Patients PD patients: $13.8 \times .80 = 11.04$ HH patients: $13.8 \times .20 = 2.76$
Project Chowan County patients forward one year to December 31, 2021, using the Chowan County Five Year AACR of 13.8%.	$64.8 \times 1.138 = 73.74$ Total Dialysis Patients
Project the number of home patients of Chowan County residents as of December 31, 2021 by increasing the percent of home patients from 21.34% to 25.00% (by 3.66%)	$73.74 \times .25 = 18.4$ PD patients: $18.4 \times .80 = 14.72$ HH patients: $18.4 \times .20 = 3.68$
Project Chowan County patients forward one year to December 31, 2022, using the Chowan County Five Year AACR of 13.8%.	$73.74 \times 1.138 = 83.9$
Project the number of home patients of Chowan County residents as of December 31, 2022 based on 25.00% of total dialysis patients.	$83.9 \times .25 = 20.975$ PD patients: $21 \times .80 = 16.78$ HH patients: $21 \times .20 = 4.2$
Applicant assumes 75% of Chowan County PD patients will be dialyzing with Chowan Home Dialysis as of December 31, 2022. This is the ending PD patient census for Chowan Home Dialysis for Operating Year 1.	$16.78 \times .75 = 12.58$ PD patients
Project Chowan County patients forward one year to December 31, 2023, using the Chowan County Five Year AACR of 13.8%.	$83.9 \times 1.138 = 95.478$
Project the number of home patients of Chowan County residents as of December 31, 2023 based on 25.00% of total dialysis patients	$95.478 \times .25 = 23.869$ PD patients: $23.869 \times .80 = 19.09$ HH patients: $23.869 \times .20 = 4.773$
Applicant assumes 75% of Chowan County PD patients will be dialyzing with Chowan Home Dialysis as of December 31, 2023. This is the ending PD patient census for Chowan Home Dialysis for Operating Year 2.	$19.09 \times .75 = 14.31$ 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, PD and HH) who are residents of Chowan County and reasonable growth projections.
- Future growth of all Chowan County ESRD patients is based on the Five-Year AACR for Chowan County.
- The applicant projection that home patient penetration of Chowan County will increase to 25% by December 31, 2021 is reasonable given that: home patient penetration of Chowan County was already at 14% as of December 31, 2018; an increase to 25% at the end of 2021 only represents an incremental increase of 3.67% per year for three years; the Executive Order on Advancing American Kidney Health issued on July 10, 2019 by President Trump; the patient census of Edgecombe Home Dialysis increasing from five PD patients as of December 31, 2017 to 35 PD patients as of December 31, 2019 as documented in the applicant response to comments; letters of support from Eastern Nephrology Associates; the fact that FMS ENA Home, LLC is a joint venture between BMA and Eastern Nephrology Associates and the applicant representation that Fresenius Medical Care has experienced a significant shift in referral numbers for home dialysis since July 2019.
- The applicant, while, if approved, only projects that it would serve 75% of the Chowan County residents who utilize PD for treatment even though it would be the only dialysis facility in Chowan County which offered PD training and support services.
- The physician letters of support in Exhibit H-4.
- The fact the applicant is a joint venture which includes Eastern Nephrology Associates.
- For OY1, the applicant is only projecting an increase of 10 PD patients in Chowan County over a four year period for a total of 16 PD patients at the end of CY2022 in a county with a 5 year AACR of 13.8% and then projecting to serve just 75% of those 16 Chowan County PD patients when there is no other dialysis facility offering PD training and support services in the service area.

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 Percent 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%

Source: Table on page 53 of the application.

*Including any 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 Edenton to provide 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.

On page 34, the applicant states that its proposal is the most effective alternative because currently patients are forced to travel out of the county for home training because there are currently no home training locations within the county.

The applicant provides supporting documentation in Exhibit E-3.

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.

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 Edenton 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 \$123,701 and initial operating expenses will be \$306,822 for a total working capital of \$430,523. 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 Financing for Working Capital: FMS ENA Home, LLC		Amount
(a)	Loans	\$
(b)	Cash or Cash Equivalents, Accumulated Reserves or Owner's Equity	\$430,523
(c)	Lines of credit	\$
(d)	Bonds	\$
(e)	Total *	\$430,523

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 need. 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.

	1 st Full Fiscal Year	2 nd Full Fiscal Year
Total Treatments	1,748	1,990
Total Gross Revenues (Charges)	\$11,001,380	\$12,519,570
Total Net Revenue	\$915,046	\$1,041,322
Average Net Revenue per Treatment	\$523	\$523
Total Operating Expenses (Costs)	\$613,644	\$654,381
Average Operating Expense per Treatment	\$351	\$329
Net Income	\$301,401	\$386,941

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.

C

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

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.*” Chowan Home Dialysis is proposed to be in Chowan County. Thus, the service area for this facility is Chowan 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 153 of the 2020 SMFP, Edenton Dialysis, a DaVita related facility, is the only dialysis facility operating in Chowan County. Edenton Dialysis provides only in-center (IC) dialysis.

Chowan County Dialysis Facilities

Dialysis Facility	Certified Stations as of 12/31/2018	Percent Utilization as of 12/31/2018	# of IC patients as of 12/31/2018
Edenton Dialysis	17	94.12%	64

Source: Table 9B of the 2020 SMFP, page 153

There are no dialysis facilities in Chowan County that provide either PD or HH training or support services.

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 currently exist within Chowan County.”

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 result in an increase in home peritoneal dialysis training and support services in the service area.
- 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 facility in the service area which does not provide home peritoneal dialysis training and support services.

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 91, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Projected FTE Staff	Projected FTE Staff
	1 st Full Fiscal Year (1/1/2022 to 12/31/2022)	2nd Full Fiscal Year (1/1/2023 to 12/31/2023)
Administrator	0.75	0.75
Home Training Nurse	0.75	0.75
Dietician	0.20	0.20
Social Worker	0.20	0.20
Maintenance	0.05	0.05
Admin/Business Office	0.20	0.20
Other: FMC Dir. Operations	0.1	0.1
Other: In-Service	0.05	0.05
Other: Chief Tech	0.05	0.05
TOTAL	2.35	2.35

The assumptions and methodology used 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, 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	
SERVICES	PROVIDER
Self-care training	On site
Home training HH PD Accessible follow-up program	Referral to Greenville Dialysis Center On site 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	Referral to Vidant Outpatient Rehabilitation, Vidant Chowan Hospital
Transportation	Roanoke Medical Transport; Chowan County Social Services

Source: Table in Section I, page 44

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 and Exhibit I.

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

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

- (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.

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 Percent 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%

Source: Table on page 53 of the application.

*Including 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 historic payor mix of actual treatment volumes of Edgecombe Home Dialysis, an existing freestanding facility for peritoneal dialysis home training and support services, which is located less than 70 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 Edenton to provide home peritoneal dialysis training and support services.

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.*” Chowan Home Dialysis is proposed to be in Chowan County. Thus, the service area for this facility is Chowan 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 153 of the 2020 SMFP, Edenton Dialysis, a DaVita related facility, is the only dialysis facility operating in Chowan County. Edenton Dialysis provides only in-center (IC) dialysis.

Chowan County Dialysis Facilities

Dialysis Facility	Certified Stations as of 12/31/2018	Percent Utilization as of 12/31/2018	# of IC patients as of 12/31/2018
Edenton Dialysis	17	94.12%	64

Source: Table 9B of the 2020 SMFP, page 153

There are no dialysis facilities in Chowan County that provide either PD or HH training or support services.

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 Chowan County. The applicant does not project to serve dialysis patients currently being served by another provider.”

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 Edenton, Chowan County. There are currently no other options to train patients choosing home dialysis within Chowan County. ... Patients will not have to leave the county for home peritoneal dialysis training and support. Consequently these patients will have a shorter commute to and from home dialysis training. 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 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 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 Edenton 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.