

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: June 28, 2024

Findings Date: July 2, 2024

Project Analyst: Gregory F. Yakaboski

Co-Signer: Lisa Pittman

Project ID #: R-12466-24

Facility: Chowan Home Dialysis

FID #: 200027

County: Chowan

Applicant: FMS ENA Home, LLC

Project: Add one home hemodialysis station at an existing home training facility

REVIEW CRITERIA

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

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

NC

FMS ENA Home, LLC (hereinafter “ENA” or “the applicant”) proposes to develop one in-center dialysis station dedicated to home hemodialysis (HHD) station at Chowan Home Dialysis, an existing home training facility. Chowan Home Dialysis is a standalone kidney disease treatment center offering training and support exclusively for peritoneal dialysis (PD) patients dialyzing at home. Chowan Home Dialysis does not have any certified dialysis stations and does not currently provide either in-center (IC) dialysis or HHD.

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 2024 State Medical Facilities Plan (SMFP) in Chapter 9, page 113, states,

“There are two types of dialysis: hemodialysis and peritoneal dialysis. Hemodialysis is the form of dialysis in which the blood is circulated outside the body through an apparatus which permits the transfer of waste through synthetic membranes. Peritoneal dialysis is the form of dialysis in which a dialysis fluid is introduced into the person’s peritoneal cavity and is subsequently withdrawn. Peritoneal dialysis is performed in the patient’s home. Hemodialysis can be performed in the patient’s home (home hemodialysis) or in an ESRD facility (in-center hemodialysis).

...

*A **dialysis station** is an individual patient treatment area that provides sufficient space to accommodate the dialysis equipment and supplies needed for routine care and any emergency care indicated. There must be sufficient separation from other dialysis stations to afford protection from cross-contamination with bloodborne pathogens.*

*An **in-center** patient receives dialysis services at the ESRD facility only.*

*A **home** patient receives hemodialysis or peritoneal dialysis in the patient’s home, except for training that is provided in an ESRD facility.”*

Chapter 9 of the 2024 SMFP, page 115, states,

“Application of the Methodologies

“ESRD services have two methodologies: the county need methodology projects need for the county and the facility need methodology projects need for a specific facility. When a county need determination exists, any current provider may apply to add stations in an existing facility, and anyone may apply to develop a new facility. When a facility need determination exists, only the facility that generated the need may apply to add stations.”

Need Determination

Chapter 9 of the 2024 SMFP provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table 9C, page 136, the county need methodology shows there is not a county need determination for additional dialysis stations in Chowan County.

In the 2024 SMFP, Table 9D, *Dialysis Station Need Determination by Facility*, page 137, shows that there is no Facility Need Determination for the Chowan Home Dialysis.

The facility need methodology in the 2024 SMFP, which is premised on a facility having historic IC utilization, has two conditions, Condition 1 and Condition 2, under which an applicant can apply to develop a new dialysis station at a facility.

The facility need methodology, on pages 116-118, of the 2024 SMFP states:

“Facility Need Determination Methodology

A dialysis facility located in a county that has no county need determination in the current SMFP may apply for additional stations under one of the two following conditions.

Condition 1: This condition pertains to new facilities, small facilities, and facilities that are both new and small (identified in Table 9A).

a. The facility’s current reported utilization must be at least 3.0 patients per station per week. For purposes of Condition 1 only, “current” means in-center utilization as of a reporting date no more than 90 days before the date the CON application is submitted.

....

Condition 2: This condition pertains to facilities certified and in operation at least 21 months as of the data cut-off date for the current SMFP (Table 9A).

a. A facility may add stations if its utilization rate reported in the current SMFP is at least 75%, or 3.0 patients per station per week or greater $[\frac{((\text{Column L}/\text{Column K})/4)}{= \text{Column M}}]$.

Chowan Home Dialysis does not have any certified in-center stations and thus has no “current” in-center utilization to report. To comply with Condition 1 above an applicant must have current in-center utilization. In addition, in-center utilization is also required to comply with Condition 2. Therefore, the applicant is not eligible under either Condition 1 or Condition 2 of the facility need methodology in the 2024 SMFP to develop a new dialysis station.

The applicant is not eligible under either the county need methodology or the facility need methodology to develop a new dialysis station.

Policies

There are no policies in the 2024 SMFP that apply to the proposed project.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is not conforming to this criterion based on the following:

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

C

The applicant proposes to develop one dialysis station at Chowan Home Dialysis, dedicated exclusively to HHD. Upon project completion, Chowan Home Dialysis will be certified for HHD and PD training and support services.

Patient Origin

On page 113, the 2022 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.*” Thus, the service area for this facility consists of Chowan County. Facilities may also serve residents of counties not included in their service area.

The applicant provides the historical patient origin for CY 2023 as shown in the table below.

County	Chowan Home Dialysis					
	Last Full FY 01/1/2023 to 12/31/2023					
	# of IC Patients	% of Total	# of HHD Patients	% of Total	# of PD Patients	% of Total
Chowan	0	0.00%	0	0.00%	4.0	21.1%
Bertie	0	0.00%	0	0.00%	3.0	15.8%
Hertford	0	0.00%	0	0.00%	1.0	5.3%
Hyde	0	0.00%	0	0.00%	1.0	5.3%
Martin	0	0.00%	0	0.00%	1.0	5.3%
Pasquotank	0	0.00%	0	0.00%	1.0	5.3%
Perquimans	0	0.00%	0	0.00%	3.0	15.8%
Tyrell	0	0.00%	0	0.00%	1.0	5.3%
Washington	0	0.00%	0	0.00%	4.0	21.1%
Total	0	0.00%	0	0.00%	19.0	100.0%

Source: Table on page 26 of the application.

The following table illustrates historic and projected patient origin for the second full fiscal year.

County	Chowan Home Dialysis					
	Second Full FY CY 2026					
	# of IC Patients	% of Total	# of HHD Patients	% of Total	# of PD Patients	% of Total
Chowan	0	0.00%	1.0	20.0%	4.0	21.1%
Bertie	0	0.00%	0	0.00%	3.0	15.8%
Hertford	0	0.00%	1.0	20.0%	1.0	5.3%
Hyde	0	0.00%	0	0.00%	1.0	5.3%
Martin	0	0.00%	0	0.00%	1.0	5.3%
Pasquotank	0	0.00%	0	0.00%	1.0	5.3%
Perquimans	0	0.00%	1.0	20.0%	3.0	15.8%
Tyrell	0	0.00%	0	0.00%	1.0	5.3%
Washington	0	0.00%	2.0	40.0%	4.0	21.1%
Total	0	0.00%	5.0	100.0%	19.0	100.0%

Source: Table on page 27 of the application.

In Section C, pages 27-35 and Section Q, pages 90-97, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported based on the following:

- ENA is currently serving 21 Chowan County IC patients with end-stage renal disease (ESRD) and 31 Chowan County patients who have some advanced stage of chronic kidney disease (CKD).
- ENA currently serves 219 patients with ESRD and 490 patients with late-stage CKD from the eight other eastern North Carolina counties (outside of Chowan) listed in the table above.
- The applicant notes that while it is reasonable to assume that patients would prefer to receive dialysis services within their home county, the catchment area for home therapies can be larger than it is for in-center dialysis as home therapy patients do not have the burden of traveling three times a week for dialysis treatment after their training is completed. Thus, it is not uncommon for facilities providing home therapies to serve patients from surrounding counties.

Analysis of Need

In Section C.4, pages 37-38, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services as summarized below.

- Chowan Home Dialysis is currently only certified for peritoneal dialysis. Peritoneal dialysis patients will either require a transplant or require hemodialysis as the peritoneal dialysis modality has an expiration date with use of a natural membrane of the patient. Thus, it is reasonable to assume that a peritoneal dialysis patient would need to convert to hemodialysis at some point during the course of their treatment if no transplant is received.
- The facility currently offers and will continue to offer peritoneal dialysis (PD) training and support services. The proposed project would allow for improved access to home hemodialysis training and support services in Chowan County and the surrounding areas.

“The existing patient population of Chowan Home Dialysis has experienced significant growth of its PD patients since it began offering services on April 21, 2022. In addition, the percentage of home dialysis patients for Chowan County has gone up 25% between December 31, 2020, and December 31, 2022, and the number of PD patients at Chown Home Dialysis has increased from 15 patients 19 patients between December 31, 2022 to December 31, 2023. Clearly, the home ESRD patient population of Chowan County

is growing, which supports the development of home hemodialysis services at the facility to ensure access to continuity of care for dialysis patients.

This facility will continue to have added value stemming from the strength of our relationship with Eastern Nephology Associates (ENA). The ENA physicians represent one of the largest and oldest group of nephrologists practicing in eastern North Carolina. The practice brings together the collaborative efforts of well qualified nephrologists to provide care for the patients choosing to dialyze at Chowan Home Dialysis.

Providing additional dedicated dialysis stations will allow the facility to take advantage of the space and enhance access to home hemodialysis as a modality of choice. Thus, utilizing available space, coupled with the development of home hemodialysis capacity will enhance patient access to care for the growing home hemodialysis modality. Developing one station at the facility will increase access to home hemodialysis training and support for residents of Chowan County and surrounding areas.”

- The applicant notes that while it is reasonable to assume that patients would prefer to receive dialysis services within their home county, the catchment area for home therapies can be larger than it is for in-center dialysis as home therapy patients do not have the burden of traveling three times a week for dialysis treatment after their training is completed. Thus, it is not uncommon for facilities providing home therapies to serve patients from surrounding counties.
- There are only two dialysis facilities operating in Chowan County, Edenton Dialysis and Chowan Home Dialysis. Neither offers HHD services.
- 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....”
- ENA is currently serving 21 Chowan County IC patients with end-stage renal disease (ESRD) and 31 Chowan County patients who have some advanced stage of chronic kidney disease (CKD).
- ENA currently serves 219 patients with ESRD and 490 patients with late-stage CKD from the eight other eastern North Carolina counties (outside of Chowan) listed in the table above identifying counties of patient origin.

- The applicant notes that while it is reasonable to assume that patients would prefer to receive dialysis services within their home county, the catchment area for home therapies can be larger than it is for in-center dialysis as home therapy patients do not have the burden of traveling three times a week for dialysis treatment after their training is completed. Thus, it is not uncommon for facilities providing home therapies to serve patients from surrounding counties.

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

- There are no other dialysis facilities offering HHD training and support services in the service area.
- The fact that peritoneal dialysis has an expiration date with use of a natural membrane patient which means that PD patients will at one point either need a transplant or require hemodialysis combined with the number of PD patients currently receiving services at Chowan Home Dialysis
- The 21 Chowan County residents who are currently IC patients with ESRD and the 31 who have CKD.
- The 709 residents of the eight eastern NC counties projected to be served by Chowan Home Dialysis with either ESRD or CKD.
- The applicant’s historical experience at Edgecombe Home Dialysis.
- Federal focus and emphasis on home dialysis pursuant to the Presidential Executive Order of July 10, 2019, in Exhibit A-1.

Projected Utilization

HHD Training Patients Projected Utilization

In Section C.5, page 39, the applicant provides projected utilization, as illustrated in the following table.

	# of HHD Patients Trained	# of PD Patients Trained
Last Full FY: CY2023	NA	11
Interim Full FY: FY2024	8-10	12
1 st Full FY: CY2025	8-10	13
2 nd Full FY: CY2026	8-10	15

In 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, 2024, to December 31, 2024 (CY2024).
- Operating Year 2 is January 1, 2025, to December 31, 2025 (CY2025).
- 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....*”
- ENA is currently serving 21 Chowan County IC patients with end-stage renal disease (ESRD) and 31 Chowan County patients who have some advanced stage of chronic kidney disease (CKD).
- ENA currently serves 219 patients with ESRD and 490 patients with late-stage CKD from the eight other eastern North Carolina counties (outside of Chowan) listed in the table above identifying counties of patient origin.
- The applicant notes that while it is reasonable to assume that patients would prefer to receive dialysis services within their home county, the catchment area for home therapies can be larger than it is for in-center dialysis as home therapy patients do not have the burden of traveling three times a week for dialysis treatment after their training is completed. Thus, it is not uncommon for facilities providing home therapies to serve patients from surrounding counties.
- There are only two dialysis facilities operating in Chowan County, Edenton Dialysis and Chowan Home Dialysis. Neither offers HHD services.
- Home dialysis offers a dialysis patient much more flexibility with regard to scheduling dialysis treatment at times that are convenient to the patient, thus improving the patient's quality of life. Home dialysis is a key concept of the President's Executive Order. Considering this Executive Order, it is reasonable to project that more patients will be referred for home dialysis. Such has certainly been the experience of Fresenius facilities, not just in North Carolina, but across the country.
- The applicant has included a letter of support in Exhibit H-4 from the medical director of the facility who is a physician at Eastern Nephrology Associates, stating support for this proposal and that he/she will refer patients for home therapies to the facility. (page 32)

- The applicant provides a comparison of Edgecombe Home Dialysis and Chowan Home Dialysis. The two facilities are both located in eastern North Carolina and are approximately 69 miles apart. The applicant states,

“Edgecombe Home Dialysis is an existing freestanding home therapies facility that offers both home hemodialysis and peritoneal dialysis training and support services. Chowan Home Dialysis is also proposing to offer both home hemodialysis and peritoneal dialysis training and support services and the applicant believes that it is reasonable to rely upon certain information from Edgecombe Home Dialysis as a model for projections of the future patient population for the proposed application, for the following reasons:

- *The Edgecombe Home Dialysis facility began as a peritoneal only dialysis facility operated in the same manner as Chowan Home Dialysis and subsequently began offering home hemodialysis services just as Chowan is proposed to be operated.*
- *Edgecombe Home Dialysis relies upon the nephrology physicians of Eastern Nephrology Associates for both patient referrals and admissions, Chowan Home Dialysis will rely upon the physicians of ENA for referrals and admissions as well.*
- *The Edgecombe Home Dialysis facility relies upon Eastern Nephrology Associates for their Medical Director; Chowan Home Dialysis will have a Medical Director from the same practice.*

...

- *Edgecombe Home Dialysis has been instrumental in creating changes within the ESRD patient population of Edgecombe County by referring more patients for home therapies. The applicant is confident that Chowan Home Dialysis will have similar results.”*
- The peritoneal dialysis modality has an expiration date with use of a natural membrane PD patients will either require a transplant or require hemodialysis as of the patient. Thus, it is reasonable to assume that a peritoneal dialysis patient would need to convert to hemodialysis at some point during the course of their treatment if no transplant is received.
- Chowan Home Dialysis began offering services on April 21, 2022, and has since experienced significant growth of its PD patients. In addition, the percentage of home dialysis patients for Chowan County has gone up 25% between December 31, 2020, and December 31, 2022, and the number of PD patients at Chown Home Dialysis has increased from 15 patients 19 patients between December 31,2022 to December 31, 2023.

- The applicant states that the basis for projections of home hemodialysis patients to be trained for OY1 and OY2 also relies, in part, on the experience of the facility staff in the area. A letter of support has been provided by the Home Therapy Area Team Lead and can be found in Exhibit C-4.
- Exhibit C-4 contains a letter dated January 11,2024 from the Home Area Team Lead of Fresenius Medical Care which states,

“Eastern Nephrology Associates has shown home penetration rates at greater than 45%, exceeding the FMC company goals of 25% of patients on a home modality by 2025. ... We currently have 19 Peritoneal Dialysis patients at FKC Chowan County Home. Peritoneal dialysis has an expiration date with use of a natural membrane patient. Meaning that these patients will at one point, or another transplanted [sic] or require Hemodialysis. Our trainings yearly for Home Hemodialysis in Chowan County has the potential for 8-10 trains a year.

...

I am in full support of this (add Home Hemodialysis Training and Support) to provide more options and care for our patients.”

- The applicant states *“That all home therapy projections are also based on the 2019 Executive Order on Advancing American Kidney Health (see Exhibit C-3) and operationalizing "experience the difference" in our in-center dialysis facilities in surrounding areas. Experience the Difference is a home hemodialysis initiative that allows in-center patients to experience the benefits of home hemodialysis to determine how they feel with that equipment and frequency versus traditional in-center dialysis three times a week. This initiative is very successful in transitioning in-center dialysis patients to home dialysis.”*
- Projected utilization is reasonable and adequately supported based on the following:
 - There are no other dialysis facilities offering HHD training and support services in the service area.
 - The fact that peritoneal dialysis has an expiration date with use of a natural membrane patient which means that PD patients will at one point either need a transplant or require hemodialysis combined with the number of PD patients currently receiving services at Chowan Home Dialysis
 - The 21 Chowan County residents who are currently IC patients with ESRD and the 31 who have CKD.

- The 709 residents of the eight eastern NC counties projected to be served by Chowan Home Dialysis with either ESRD or CKD.
- The applicant's historical experience at Edgecombe Home Dialysis.
- Federal focus and emphasis on home dialysis pursuant to the Presidential Executive Order of July 10, 2019, in Exhibit A-1.
- The medical director's letter of support in Exhibit H-4.
- The fact that Eastern Nephrology Associates are one of the members of the joint venture which submitted this application.

Home Hemodialysis Projected Utilization

In Section C, pages 29-35, and in the Form C Utilization subsection of Section Q, the applicant provides the assumptions and methodology used to project patient utilization for HHD, which are summarized below.

- The applicant begins its utilization projections on December 31, 2024, the date the project is proposed to be certified and the Chowan HHD patient who signed a letter of support is projected to transfer their care based on convenience of location to Chowan Home Dialysis.
- The Chowan County Five-Year AACR as published in Table 9B, page 132 of the 2024 SMFP is 0.3 percent. The applicant projects growth of the Chowan County HHD patient who signed a letter of support and is projected to transfer care to Chowan Home Dialysis at 0.3 percent.
- The applicant projects that four HHD patients residing in Washington, Hertford and Perquimans who have signed letters of support will transfer their care to Chowan Home Dialysis upon project completion.
- The applicant assumes no population growth for the four HHD patients residing outside of Chowan County and adds them to the calculations when appropriate.
- The new station is projected to be certified by December 31, 2024. OY1 is CY 2025. OY2 is CY 2026.

In Section C, page 35, and in the Form C Utilization subsection of Section Q, the applicant provides the calculations used to project the patient census for OY1 and OY2, as summarized in the table below.

Home Hemodialysis

Begin with the one home hemodialysis patient from Chowan County expected to transfer to the facility on December 31, 2024.	1.0
Add the four home dialysis patients from Hertford, Perquimans and Washington County expected to transfer to the facility on December 31, 2024.	$1.0 + 4.0 = 5.0$
Project the Chowan County patient census forward for 12 months to December 31, 2025.	$1.0 \times 1.003 = 1.0$
Add the four patients from other counties. This is the projected ending census for Operating Year One.	$1.0 + 4.0 = 5.0$
Project the Chowan County patient census forward for 12 months to December 31, 2026.	$1.0 \times 1.003 = 1.0$
Add the four patients from other counties. This is the projected ending census for Operating Year Two.	$1.0 + 4.0 = 5.0$

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

- The applicant bases the beginning HHD patient census with the one Chowan County HHD patient projected to transfer their care to Chowan Home Dialysis upon project completion.
- The applicant projects growth of the Chowan County patient census using the Chowan County Five-Year AACR of 0.3%, as published in the 2024 SMFP.
- The applicant adds the four in-center patients residing in other counties for future projections, with no growth.

Peritoneal Dialysis Projected Utilization

In Section C, pages 35-36, and in the Form C Utilization subsection of Section Q, the applicant provides the assumptions and methodology used to project patient utilization for PD, which are summarized below.

- The applicant begins projections with the facility census as of December 31, 2023.
- The proposed project is projected to be certified by December 31, 2024. OY1 is CY 2025. OY2 is CY 2026.
- As of December 31, 2023, there were four patients who are residents of Chowan County utilizing the facility for PD services.
- The Chowan County Five-Year AACR as published in Table 9B, page 132 of the 2024 SMFP is 0.3 percent.

- The applicant projects growth of the PD patients from Chowan County PD patients at 0.3 percent.
- As of December 31, 2023, the facility also served 15 PD patients residing in Bertie, Hertford, Hyde, Martin, Pasquotank, Perquimans, Tyrell and Washington Counties. Hertford and Perquimans County are contiguous to Chowan County. The applicant projects that all of these patients will continue dialysis at Chowan Home Dialysis as a function of patient choice, especially given that home dialysis patients do not travel three times a week for treatment (once their training is completed) like in-center patients.
- The applicant does not project any growth for the 15 PD patients residing outside of Chowan County and adds them to the calculations when appropriate.

In Section C, page 36, and in the Form C Utilization subsection of Section Q, the applicant provides the calculations used to project the patient census for OY1 and OY2, as summarized in the table below.

Peritoneal Dialysis Methodology

Begin with the Chowan County PD patient population as of December 31, 2023.	4.0
Project the Chowan County patient population forward one year to December 31, 2024, using a 0.3% growth rate commensurate with the growth rate in the 2024 SMFP.	$4.0 \times 1.003 = 4.0$
Add the 15 patients from other counties. This is the projected census for Interim Year One.	$4.0 + 15.0 = 19.0$
Project the Chowan County patient population forward one year to December 31, 2025, using a 0.3% growth rate commensurate with the growth rate in the 2024 SMFP.	$4.0 \times 1.003 = 4.0$
Add the 15 patients from other counties. This is the projected census for Operating Year One.	$4.0 + 15.0 = 19.0$
Project the Chowan County patient population forward one year to December 31, 2026, using a 0.3% growth rate commensurate with the growth rate in the 2024 SMFP.	$4.0 \times 1.003 = 4.0$
Add the 15 patients from other counties. This is the projected census for Operating Year Two.	$4.0 + 15.0 = 19.0$

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

- The applicant bases the beginning PD patient census on the historical PD patients residing in Chowan County as of December 31, 2023.
- The applicant projects growth of the Chowan County patient census using the Chowan County Five-Year AACR of 0.3%, as published in the 2024 SMFP.
- The applicant adds the 15 PD patients residing in other counties for future projections, with no growth.

Access to Medically Underserved Groups

In Section C. page 40, the applicant states:

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

The applicant provides the estimated percentage for each medically underserved group during the 2nd full fiscal year, as shown in the following table.

Group	Estimated Percentage of Total Patients during the Second Full Fiscal Year
Low-income persons	38.89%
Racial and ethnic minorities	55.56%
Women	38.89%
Persons with disabilities	0.00%
Persons 65 and older	50.00%
Medicare beneficiaries	66.67%
Medicaid recipients	38.89%

Source: Table on page 41 of the application.

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on Chowan Home Dialysis’s historical facility experience.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

- Supplemental information requested by the Agency
- Information publicly available during the review and used by the Agency

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

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA

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

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

NC

The applicant proposes to develop one dialysis station at Chowan Home Dialysis, dedicated exclusively to HHD. Upon project completion, Chowan Home Dialysis will be certified for HHD and PD training and support services.

In Section E, page 49, the applicant states that there were no other alternatives considered and any other alternative would not support the 2019 President's Executive Order on Advancing American Kidney Health and would not enhance access to dialysis care.

On page 49, the applicant states:

“At the present time, there are only two dialysis facilities operating in Chowan County, Edenton Dialysis which only offers in-center dialysis and Chowan Home Dialysis which only offers peritoneal dialysis. ... The applicant believes that offering home hemodialysis training and support services to patients of Chowan County and surrounding areas would bring those services closer to the patient's residence, would be more convenient and would enhance access to care for the patients of the area.”

However, the applicant does not adequately demonstrate that the alternative proposed in this application is the most effective alternative to meet the need because the application is not

conforming to all other statutory and regulatory review criteria. An application that cannot be approved cannot be an effective alternative to meet the need.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to develop one dialysis station at Chowan Home Dialysis, dedicated exclusively to HHD. Upon project completion, Chowan Home Dialysis will be certified for HHD and PD training and support services.

Capital and Working Capital Costs

In Section Q, Form F.1a, page 101, the applicant projects the total capital cost of the project, as shown in the table below.

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

In Section Q, pages 101-102, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on what is needed to operate the facility, such as patient chairs and the water treatment system.

Availability of Funds

In Section F.2, page 50, 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	\$0	\$0
Accumulated reserves or OE *	\$3,750	\$3,750
Bonds	\$0	\$0
Other	\$0	\$0
Total Financing	\$3,750	\$3,750

* OE = Owner's Equity

On page 52, the applicant states that there will be no start-up costs or initial operating costs for the existing facility.

Exhibit F-2 contains a letter dated January 16, 2024, from the VP Corporate Tax North America of Fresenius Medical Holdings, Inc., the ultimate parent company of FMS ENA Home, LLC, stating their commitment to fund the capital needs of the project through accumulated reserves. The letter states the Fresenius Medical Holdings' 2022 consolidated balance sheet reflected \$446 million in cash and over \$25 billion in total assets to fund the project.

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

Financial Feasibility

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

Chowan Home Dialysis	1 st Full FY	2 nd Full FY
	CY2025	CY 2026
Total Treatments	3,555	3,557
Total Gross Revenues (Charges)	\$22,362,408	\$22,375,028
Total Net Revenue	\$1,450,467	\$1,451,278
Average Net Revenue per Treatment	\$408	\$408
Total Operating Expenses (Costs)	\$1,310,027	\$1,319,775
Average Operating Expense per Treatment	\$369	\$371
Net Income	\$140,439	\$131,503

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
 - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
 - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

NC

The applicant proposes to develop one dialysis station at Chowan Home Dialysis, dedicated exclusively to HHD. Upon project completion, Chowan Home Dialysis will be certified for HHD and PD training and support services.

On page 113, the 2024 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.*” The proposed dialysis station would be located at the Chowan Home Dialysis facility in Chowan County. Thus, the service area for this facility consists of Chowan County. Facilities may also serve residents of counties not included in their service area.

Per Table 9A of the 2024 SMFP, there is one kidney disease treatment center providing dialysis services in Chowan County. The table below lists the existing and approved facilities, certified stations, and utilization of dialysis facilities in Chowan County as of December 31, 2022.

Facility Name	Certified Stations as of 12/31/2022	# IC Patients as of 12/31/2022	Utilization by Percent as of 12/31/2022	Patients Per Station Per Week
Edenton Dialysis	20	57	71.25%	2.85
Total	20	57		

Source: 2024 SMFP, Table 9A, page 120.

In Section G, pages 57-58, 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:

“The application is requesting to increase the number of home hemodialysis stations in a dialysis facility dedicated to home hemodialysis or peritoneal dialysis training as stated in 10A NCAC 14C .2203(d). This application does not involve developing any additional in-center dialysis stations that are included in the county inventory of stations.”

However, the applicant does not adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved services in the service area because the proposal would result in an additional dialysis station for which there is no county need or facility need determination.

Thus, the proposed project would result in unnecessary duplication of existing or approved health service capabilities or facilities.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- Information publicly available during the review and used by the Agency

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

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

C

The applicant proposes to develop one dialysis station at Chowan Home Dialysis, dedicated exclusively to HHD. Upon project completion, Chowan Home Dialysis will be certified for HHD and PD training and support services.

In Section Q, page 113 the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Projected FTE Staff	
	Current	Projected
	As of 1/11/2024	2 nd Full FY CY 2026
Administrator (FMC Clinic Manager)	0.50	0.50
Home Training Nurse	2.00	2.00
Technicians (PCT)	1.00	1.00
Dietician	0.50	0.50
Social Worker	0.50	0.50
Maintenance	0.50	0.50
Administrative/Business Office	0.50	0.50
Other: FMC Director of Operations	0.50	0.33
Other: Chief Technician	0.10	0.10
Other: FMC In-Service	0.10	0.10
TOTAL	6.20	6.03

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.4. In Section H, pages 59-60, the applicant describes the methods to be used to recruit or fill new positions and its existing training and continuing education programs.

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

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 all the reasons described above.

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

C

The applicant proposes to develop one dialysis station at Chowan Home Dialysis, dedicated exclusively to HHD. Upon project completion, Chowan Home Dialysis will be certified for HHD and PD training and support services.

Ancillary and Support Services

In Section I, page 61, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 61-66, the applicant explains how each ancillary and support service is or will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available.

Coordination

In Section I, page 66, the applicant describes its existing and proposed relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on following:

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

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

NA

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

- (11) Repealed effective July 1, 1987.

- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

The applicant does not propose to construct any new space or renovate any existing space as part of the proposed project.

Therefore, Criterion (12) is not applicable to this review.

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

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

C

In Section L, page 74, the applicant provides the historical payor mix during CY2022 for Chowan Home Dialysis for the proposed services, as shown in the table below.

**Chowan Home Dialysis
 Historical Payor Mix CY2022**

Payment Source	IC Dialysis		HHD		PD	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	0.0	0.0%	0.0	0.0%	0.0	0.00%
Insurance*	0.0	0.0%	0.0	0.0%	2.5	16.79%
Medicare*	0.0	0.0%	0.0	0.0%	11.9	79.24%
Medicaid*	0.0	0.0%	0.0	0.0%	0.6	3.97%
Other (VA)	0.0	0.0%	0.0	0.0%	0.0	0.00%
Total	0.0	0.0%	0.0	0.0%	15.0	100.00%

Totals may not sum due to rounding

*Including any managed care plans

In Section L, page 75, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	38.9%	52.0%
Male	61.1%	48.0%
Unknown		
64 and Younger	50.0%	73.8%
65 and Older	50.0%	26.2%
American Indian		0.6%
Asian		0.7%
Black or African-American	55.6%	32.4%
Native Hawaiian or Pacific Islander	0.0%	0.3%
White or Caucasian	38.9%	64.2%
Other Race		5.7%
Declined / Unavailable	5.6%	

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the applicant adequately documents 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. Therefore, the application is conforming to this criterion.

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 76, the applicant states:

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

In Section L, page 76, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 77, 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.

**Chowan Home Dialysis
 Projected Payor Mix CY2026**

Payment Source	IC Dialysis		HHD		PD	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-pay	0.0	0.0%	0.0	0.00%	0.0	0.00%
Insurance*	0.0	0.0%	1.0	20.67%	3.2	16.79%
Medicare*	0.0	0.0%	4.0	79.33%	15.1	79.24%
Medicaid*	0.0	0.0%	0.0	0.00%	0.8	3.97%
Other (VA)	0.0	0.0%	0.0	0.00%	0.0	0.00%
Total	0.0	0.0%	5.0	100.00%	19.0	100.00%

Totals may not sum due to rounding

*Including any managed care plans

Source: Table on page 77 of the application.

The Project Analyst notes that on page 77 that applicant states,

“The format of the above table (as prescribed by the CON Agency) has requested the number of patients and percent of patients by payor source category. Fresenius Medical Care reporting does not lend itself to reporting payor mix based solely upon the whole patient. Fresenius Medical Care facilities calculate payor mix based upon treatment volumes; this provides a more detailed analysis of payor source reimbursement. For example, if payor mix were based upon individual patients, if a patient changed insurance coverage throughout the year, or converted to Medicare at some point in the year, a calculation based solely on patients would distort the revenue picture. However, basing the payor mix on treatment volumes provides a clear indication to Fresenius Medical Care (and of course INS) of the source of revenue.

The above table reports fractional patients. As previously noted, Fresenius Medical Care corporate accounting procedures do not allow for counting patients, but rather the payor source is determined based upon treatment reimbursement. It is not uncommon for patients to change insurance carriers. This primarily involves changes from commercial insurance to Medicare; Medicare generally becomes the patient primary insurance after 30 months of commercial insurance.”

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 79.33% of home hemodialysis services will be provided to Medicare patients.

On page 77, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the

project. The projected payor mix is reasonable and adequately supported based on the following:

- The applicant relied on the historical home hemodialysis payor mix at the Edgecombe Home Dialysis facility during FY 2021. As stated on page 73 of the application, Edgecombe Home Dialysis began as a freestanding peritoneal dialysis facility and operated in the same manner as Chowan Home. Subsequently, the facility began offering home hemodialysis services just as Chowan is proposing in this application. Edgecombe Home Dialysis relies upon the same nephrology physicians (ENA) for both patient referrals, admissions and medical director oversight, just as Chowan Home Dialysis, and Edgecombe Home Dialysis is located only 69 miles away.
- Medicaid patients will have access to the facility as documented by the facility's Medicaid Certification letter in Exhibit 0-2.
- The applicant relied on the historical peritoneal dialysis payor mix (FY 2022) at Chowan Home Dialysis.

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- 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 or analysis*) 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 79, 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

The applicant proposes to develop one dialysis station at Chowan Home Dialysis, dedicated exclusively to HHD. Upon project completion, Chowan Home Dialysis will be certified for HHD and PD training and support services.

In Section M, page 80, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-1. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes.

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 all the reasons described above.

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

NC

The applicant proposes to develop one dialysis station at Chowan Home Dialysis, dedicated exclusively to HHD. Upon project completion, Chowan Home Dialysis will be certified for HHD and PD training and support services.

Per Table 9A of the 2024 SMFP, there is one kidney disease treatment center providing dialysis services in Chowan County. The table below lists the existing and approved facilities, certified stations, and utilization of dialysis facilities in Chowan County as of December 31, 2022.

Facility Name	Certified Stations as of 12/31/2022	# IC Patients as of 12/31/2022	Utilization by Percent as of 12/31/2022	Patients Per Station Per Week
Edenton Dialysis	20	57	71.25%	2.85
Total	20	57		

Source: 2024 SMFP, Table 9A, page 120.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 81, the applicant states:

“The applicant does not project to serve dialysis patients currently being served by another provider. The projected patient population for the facility begins with patients who are currently being served at the facility and at other facilities owned or operated by Fresenius Medical Care and is grown by reasonable growth rates as discussed in Section C of this application.

...

This facility also has added value stemming from the strength of our relationship with nephrology physicians of Eastern Nephrology Associates. These nephrologists have been practicing in Chowan County and surrounding counties, serving the ESRD patients of the area for many years. The practice brings together the collaborative efforts of a team of very qualified nephrologists to provide care for the patients choosing to dialyze at Chowan Home Dialysis.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 82, the applicant states:

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

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

Regarding the impact of the proposal on quality, in Section N, page 82, the applicant states:

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

See also Section O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 82, the applicant states:

“All Fresenius related facilities in North Carolina have a history of providing dialysis services to the underserved population of North Carolina. The Form O identifies all Fresenius related operational and/or CON approved facilities across North Carolina. Each of those facilities has a patient population which includes low-income persons, racial or ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.”

See also Section L of the application and any exhibits.

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

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

Conclusion

The Agency reviewed the:

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

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

(19) Repealed effective July 1, 1987.

- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Section Q, pages 115-119, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of over 120 of this type of facility located in North Carolina.

In Section O, page 87, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents resulting in immediate jeopardy had not occurred in any of these facilities. After reviewing and considering information provided by the applicant, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

G.S. 131E-183 (b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The application is conforming with all applicable Criteria and Standards for End-Stage Renal Disease Services. The specific criteria are discussed below.

SECTION .2200 – CRITERIA AND STANDARDS FOR END-STAGE RENAL DISEASE SERVICES

10A NCAC 14C .2201 DEFINITIONS

The following definitions shall apply to this Section:

- (1) “Dialysis” means the artificially aided process of transferring body wastes from a person's blood to a dialysis fluid to permit discharge of the wastes from the body.
- (2) “Dialysis facility” means a kidney disease treatment center as defined in G.S. 131E176(14e).

(3) “Dialysis station” means the treatment area in a dialysis facility used to accommodate the equipment and supplies needed to perform hemodialysis on a single patient.

(4) “Hemodialysis” means the form of dialysis in which the blood is circulated outside the body through equipment that permits transfer of waste through synthetic membranes.

(5) “Home hemodialysis” means hemodialysis performed in a location other than a dialysis facility by the patient after the patient is trained in a dialysis facility to perform the hemodialysis.

(6) “In-center hemodialysis” means hemodialysis performed in a dialysis facility.

(7) “Peritoneal dialysis” means the form of dialysis in which a dialysis fluid is introduced into the person's peritoneal cavity and is subsequently withdrawn. This form of dialysis is performed in a location other than a dialysis facility by the patient after the patient is trained in a dialysis facility to perform the peritoneal dialysis.

10A NCAC 14C .2203 PERFORMANCE STANDARDS

(a) An applicant proposing to establish a new dialysis facility for in-center hemodialysis services shall document the need for at least 10 dialysis stations based on utilization of 2.8 in-center patients per station per week as of the end of the first full fiscal year of operation following certification of the facility. An applicant may document the need for fewer than 10 stations if the application is submitted in response to an adjusted need determination in the State Medical Facilities Plan for fewer than 10 stations.

-NA- The applicant is not proposing to establish a new dialysis facility for in-center hemodialysis.

(b) An applicant proposing to increase the number of in-center dialysis stations in:

(1) an existing dialysis facility; or

(2) a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first full fiscal year of operation following certification of the additional stations.

-NA- The applicant is not proposing to increase the number of in-center dialysis stations in any facility.

(c) An applicant proposing to establish a new dialysis facility dedicated to home hemodialysis or peritoneal dialysis training shall document the need for the total number of home hemodialysis stations in the facility based on training six home hemodialysis patients per

station per year as of the end of the first full fiscal year of operation following certification of the facility.

-NA- The applicant is not proposing to establish a new dialysis facility dedicated to home hemodialysis or peritoneal dialysis.

(d) An applicant proposing to increase the number of home hemodialysis stations in a dialysis facility dedicated to home hemodialysis or peritoneal dialysis training shall document the need for the total number of home hemodialysis stations in the facility based on training six home hemodialysis patients per station per year as of the end of the first full fiscal year of operation following certification of the additional stations.

-C- In Section C.5, page 39, the applicant documents the need for a total of one home hemodialysis station in the facility based on training 8-10 home hemodialysis patients per year as of the end of the first full fiscal year of operation (CY2024) following certification of the additional station. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

(e) The applicant shall provide the assumptions and methodology used for the projected utilization required by this Rule.

-C- In Section C, pages 27-29, and Section Q, Form C, pages 91- 100 the applicant provides the assumptions and methodology used to project utilization for the HHD station. The discussion regarding projected utilization and occupancy rates found in Criterion (3) is incorporated herein by reference.