

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: December 19, 2025

Findings Date: December 19, 2025

Project Analyst: Crystal Kearney

Co-Signer: Mike McKillip

Project ID #: L-12696-25

Facility: Edgecombe Home Dialysis

FID #: 150397

County: Edgecombe

Applicant(s): FMS ENA Home, LLC

Project: Relocate no more than one dialysis station from FMC Tarboro to be used for home hemodialysis training and support for a total of no more than 2 stations upon project completion

### 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.

NA

FMS ENA Home, LLC (hereinafter referred to as “the applicant” or Edgecombe Home Dialysis) proposes to relocate no more than one dialysis station from FMC Tarboro to be used for home hemodialysis training and support for a total of no more than 2 stations located at Edgecombe Home Dialysis in Tarboro upon project completion.

The applicant does not propose to develop any beds or services or acquire any medical equipment for which there is a need determination in the 2025 SMFP or offer a new institutional health service for which there are any policies in the 2025 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- (2) Repealed effective July 1, 1987.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, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to relocate no more than one dialysis station from FMC Tarboro to be used for home hemodialysis training and support for a total of no more than 2 stations upon project completion.

**Patient Origin**

On page 113, the 2025 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 Edgecombe County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates historical and projected patient origin.

<b>Edgecombe Home Dialysis Historical Patient Origin</b>						
<b>Last Full FY</b>						
<b>CY 2024</b>						
<b>County</b>	<b># of IC Patients</b>	<b>% of Total</b>	<b># of HH Patients</b>	<b>% of Total</b>	<b># of PD Patients</b>	<b>% of Total</b>
Edgecombe			3.0	75.0%	22.0	61.1%
Beaufort					1.0	2.8%
Bertie					1.0	2.8%
Chowan					1.0	2.8%
Franklin					1.0	2.8%
Halifax					2.0	5.6%
Nash			1.0	25.0%		
Pitt					1.0	5.6%
Washington					1.0	2.8%
Wayne					1.0	2.8%
Wilson					4.0	11.1%
<b>Total</b>			<b>4.0</b>	<b>100.0%</b>	<b>36.0</b>	<b>100.0%</b>

Source: Section C, page 22 of the application

<b>FMC Tarboro Historical Patient Origin</b>						
<b>Last Full FY</b>						
<b>CY 2024</b>						
<b>County</b>	<b># of IC Patients</b>	<b>% of Total</b>	<b># of HH Patients</b>	<b>% of Total</b>	<b># of PD Patients</b>	<b>% of Total</b>
Edgecombe	59.0	93.7%				
Halifax	2.0	3.2%				
Nash	1.0	1.6%				
Pitt	1.0	1.6%				
<b>Total</b>	<b>63.0</b>	<b>100.0%</b>				

Source: Section C, page 23 of the application

<b>Edgecombe Home Dialysis Historical Patient Origin</b>						
<b>Second Full FY</b>						
<b>CY 2027</b>						
<b>County</b>	<b># of IC Patients</b>	<b>% of Total</b>	<b># of HH Patients</b>	<b>% of Total</b>	<b># of PD Patients</b>	<b>% of Total</b>
Edgecombe			3.9	79.5%	28.5	67.1%
Beaufort					1.0	2.4%
Bertie					1.0	2.4%
Chowan					1.0	2.4%
Franklin					1.0	2.4%
Halifax					2.0	4.7%
Nash			1.0	20.5%		
Pitt					2.0	4.7%
Washington					1.0	2.4%
Wayne					1.0	2.4%
Wilson					4.0	9.4%
<b>Total</b>			<b>4.9</b>	<b>100.0%</b>	<b>42.5</b>	<b>100.0%</b>

Source: Section C, page 23 of the application

In Section C, pages 23-25, the applicant provides the assumptions and methodology used to project its patient origin. The proposed project is to relocate one existing dialysis station from FMC Tarboro to Edgecombe Home Dialysis for a total of two dialysis stations upon project completion. The applicant’s assumptions are reasonable and adequately supported because both are existing stations and the station proposed to be relocated in this project will be used for home hemodialysis (HHD) training and support services.

**Analysis of Need**

In Section C, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 26-28, the applicant states:

- The applicant states that Edgecombe County has experienced a surge in its home dialysis patient population over the last few years , as shown in the table below.

<b>Edgecombe County Home Therapy Patients</b>						
	<b>12/31/20</b>	<b>12/31/21</b>	<b>12/31/22</b>	<b>12/31/23</b>	<b>12/31/24</b>	<b>4-Year CAGR</b>
# of HHD Patients	4	8	7	10	7	15.01%
# of PD Patients	32	27	22	33	36	2.99%
<b>Total # of HT Patients</b>	<b>36</b>	<b>35</b>	<b>29</b>	<b>43</b>	<b>43</b>	<b>4.54%</b>

HT= Home Therapy  
 Source: Section C, page 27 of the application

- The applicant states there is growth in home dialysis statewide.
- The applicant states that the HHD patients compare the Dec. 31, 2023, data (755 patients) and the Dec. 31, 2024, data (788 patients) reported in the patient origin reports for the 2025 and the draft 2026 SMFP, you'll see that there has been an increase of 4.37% statewide in HHD patients.

	<b>2025 SMFP</b>	<b>Proposed 2026 SMFP</b>	
	<b>Dec.31, 2023</b>	<b>Dec. 31, 2024</b>	<b>% Increase</b>
<b>HHD Patients</b>	75	94	25.33%
<b>PD Patients</b>	326	369	13.19%
<b>Total Home Patients</b>	401	463	15.46%

Source: Section C, page 27 of the application

- The applicant states that the ENA physicians will continue to refer more patients to the facility for home dialysis.
- The applicant states that the relocation of this station will help to address the surge in home dialysis patients and increase access to home hemodialysis training and support services in Edgecombe County.
- The applicant states that the home dialysis affords the patient maximum flexibility with scheduling treatment at times which are convenient, and in the patient's residence. The patient has total control of the treatment, which leads to patient compliance and fewer missed treatment rates.
- The applicant states that Edgecombe Home Dialysis does have existing space which can be used to expand home hemodialysis. Providing an additional dedicated dialysis station will allow the facility to take advantage of the space and enhance access to home hemodialysis as a modality of choice and will eliminate the need for home hemodialysis patients to travel outside of the county for this modality.
- The applicant states that approval of this application will allow the applicant to relocate one existing hemodialysis station to be used for home hemodialysis training and support of patients choosing hemodialysis. This will enhance patient training opportunities and ultimately will allow Edgecombe Home Dialysis to enable more patients to dialyze at home in a convenient setting, at times which are convenient for the patient.
- The applicant states that the applicant has identified the population to be served as 4.6 home hemodialysis and 40.7 peritoneal dialysis patients dialyzing with the facility as of the end of the first Operating Year of the project.

The information is reasonable and adequately supported based on the facility's projected growth in the home therapy patient population.

**Projected Utilization**

In Section Q, Form C, page 80, the applicant provides historical and projected utilization, as illustrated in the following table.

<b>Form C Utilization</b>	<b>Last Full FY CY 2024</b>	<b>Interim Full FY CY2025</b>	<b>Certification CY 2026</b>	<b>1<sup>st</sup> Full FY CY 2027</b>	<b>2<sup>nd</sup> Full FY CY 2028</b>
<b>Home Hemodialysis Patients</b>					
# of Patients at the Beginning of the Year	3	4	4	4	5
# of Patients at the End of the Year	4	4	4	5	5
Average # of Patients during the Year	4	4	4	5	5
# of Treatments/Patient/Year	148	148	148	148	148
<b>Total # of Treatments</b>	<b>582</b>	<b>570</b>	<b>638</b>	<b>670</b>	<b>705</b>
<b>Peritoneal Dialysis Patients</b>					
# of Patients at the Beginning of the Year	29	36	37	39	41
# of Patients at the End of the Year	36	37	39	41	43
Average # of Patients during the Year	33	37	38	40	42
# of Treatments/Patient/Year	148	148	148	148	148
<b>Total # of Treatments</b>	<b>4,843</b>	<b>5,437</b>	<b>5,663</b>	<b>5,903</b>	<b>6,160</b>
<b>Total Patients</b>					
# of Patients at the Beginning of the Year	32	40	42	43	45
# of Patients at the End of the Year	40	42	43	45	47
Average # of Patients during the Year	36	41	43	44	46
# of Treatments/Patient/Year	148	148	148	148	148
<b>Total # of Treatments</b>	<b>5,425</b>	<b>6,007</b>	<b>6,300</b>	<b>6,574</b>	<b>6,865</b>

In Section Q, pages 81-82 , the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

**Home Dialysis Assumptions**

1. Edgecombe Home Dialysis is an existing dialysis facility that is currently certified with one station and both HHD and PD training and support services. The applicant states that this facility is listed in Chapter 9 Table 9E: Inventory of Dialysis Home Training Facilities in the 2025 SMFP. The applicant states Edgecombe Home Dialysis is the only dialysis provider offering a home therapy program in Edgecombe County.
2. The applicant begins projections of the future patient population to be served with the Edgecombe County facility census as of December 31, 2024. This information was reported on the 2024 ESRD Data Collection Form for the period ending December 31, 2024, and was submitted to DHSR Healthcare Planning in February 2025 and is reflected in the Chapter 9: Dialysis Data by County of Patient Origin Report for the Proposed 2026 SMFP.
3. Edgecombe County has experienced a surge in its home dialysis patient population over the last few years, as shown in the table below.

<b>Edgecombe County Home Therapy Patients</b>				
	12/31/2022	12/31/2023	12/31/2024	<b>2-Year CAGR</b>
<b>Total # of HT Patients</b>	<b>29</b>	<b>43</b>	<b>43</b>	<b>21.77%</b>

HT= Home Therapy

Source: Chapter 9 : Dialysis Data by County of Patient Origin Reports

- The applicant believes that this surge in home dialysis patients is a direct result of a national emphasis on home dialysis and an increase in referrals and admission by the ENA physicians and their commitment to home dialysis because of the improved quality of life that it offers to ESRD patients. The applicant expects that the ENA physicians will continue to refer more patients to the facility for home dialysis.
4. The applicant will project growth of the Edgecombe County patient population using a 6.7% growth rate commensurate with the 5-Year Average Annual Change Rate (5-Year AACR) for Edgecombe County published in the 2025 SMFP.
  5. The facility also has one HHD patient residing in Nash County and 14 PD patients residing in Beaufort, Bertie, Chowan, Franklin, Halifax, Pitt, Washington, Wayne and Wilson County. The applicant states most of these counties are not contiguous to Edgecombe County, it is important to note that home dialysis patients do not travel 3 x a week for treatment as in-center patients. Home dialysis patients self-dialyze at home and report to a facility once a month for routine maintenance/follow-up. Thus, it is not uncommon for a facility to follow home dialysis patients from other counties.
  6. The relocation project is projected to be certified as of December 31, 2026.  
Operating Year 1 is the period from January 1 - December 31, 2027.  
Operating Year 2 is the period from January 1 - December 31, 2028.

**Home Dialysis Projections**

	HHD	PD
Begin with the Edgecombe County patient population as of December 31, 2024	3.0	22.0
Project in Edgecombe County patient population forward to December 31, 2024	$3.0 \times 1.067 = 3.2$	$22 \times 1.067 = 23.5$
Add the patients from other counties. This is the projected ending census for Interim Year 1.	$3.2 + 1 = 4.2$	$23.5 + 14 = 37.5$
Project the Edgecombe County patient population forward for one year to December 31, 2026.	$3.2 \times 1.067 = 3.4$	$23.5 \times 1.067 = 25.0$
Add the patients from other counties. This is the projected ending census for Interim Year 1.	$3.4 + 1 = 4.4$	$25.0 + 14.0 = 39.0$
Project the Edgecombe County patient population forward for one year to December 31, 2027.	$3.4 \times 1.067 = 3.6$	$25.0 \times 1.067 = 26.7$
Add the patients from other counties. <b>This is the ending of Operating Year 1.</b>	$3.6 + 1 = 4.6$	$26.7 + 14.0 = 40.7$
Project the Edgecombe County patient population forward for one year to December 31, 2028.	$3.6 \times 1.067 = 3.9$	$26.7 \times 1.067 = 28.5$
Add the patients from other counties. <b>This is the end of Operating Year 2.</b>	$3.9 + 1 = 4.9$	$28.5 + 14 = 42.5$

Source: Section Q, page 82 of the application

Summary: Based upon these calculations, BMA projects to serve the following number of patients for the Operating Years 1 & 2.

Edgecombe Home Dialysis	Operating Year 1	Operating Year 2
Home Hemodialysis	4.6	4.9
Peritoneal Dialysis	40.7	42.5

Source: Section Q, page 82 of the application

The applicant proposes to relocate one existing dialysis station from FMC Tarboro to Edgecombe Home Dialysis for a total of two dialysis stations upon project completion. Both the existing station and the station proposed to be relocated in this project will be used exclusively for home hemodialysis (HHD) training and support services. Edgecombe Home Dialysis is an existing dialysis facility listed in Table 9E: Inventory of Dialysis Home Training

Facilities in the 2025 SMFP and offers both HHD and peritoneal dialysis (PD) training and support services. The dialysis facility will offer home hemodialysis and peritoneal training and support services, as illustrated in the following table

	# of Home Hemodialysis Patients Trained*	# of Peritoneal Dialysis Patients Trained*
Last Full FY 2024	3.0	21.0
Interim Full FY 2025	6.9	12.0
Interim Full FY 2026	6.9	17.0
1 <sup>st</sup> Full FY of Operation	13.8	22.0
2 <sup>nd</sup> Full FY of Operation	27.6	27.0

\*Report the total number of patients that started training during the year even if they did not complete training during the same year or never completed the training.

Source: Section C, page 29 of the application

- The applicant states that the facility has started training a total of four HHD patients and seven PD patients.
- The applicant states that the projections of HHD patients to be trained at Edgecombe Home Dialysis for Interim Year 2025-2026 is based upon the facility performance in the first seven months of this year annualized and the applicant projects that it will train an additional two HHD patients per month for the first two operating years of the project.
- The applicant states that Projections of PD patients to be trained at Edgecombe Home Dialysis for Interim Year 2025 is based upon the facility performance in the first seven months of this year annualized the applicant projects it will train five additional PD patients in the 2nd interim year and the first two full operating years of the project.

The projected utilization is reasonable and supported based on the following:

- The applicant states that the year over year growth of chronic kidney disease (CKD) and ESRD patient populations in the market seen by the ENA physicians;
- The applicant states that the increase in referrals for home dialysis in the service area has been increasing and exceeding home growth in other areas and is projected to continue going forward;
- The applicant states that Edgecombe Home is now the only dialysis provider in the service area that offers home dialysis, thus home dialysis referrals at this facility is projected to continue going forward; and
- The applicant states that the Kidney Care Advocates and Patient Advocates complete Lobby days, home therapy education and home dialysis tours for CKD patients on a regular basis to allow them to see the many benefits of home dialysis

**Access to Medically Underserved Groups**

In Section C, page 30-31, the applicant states:

*“Fresenius Medical Care and its related facilities in North Carolina have historically provided substantial care and services to all persons in need of dialysis services,*

*regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an underserved person.”*

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons	26.7%
Racial and ethnic minorities	80.0%
Women	48.9%
Persons with Disabilities	17.8%
Persons 65 and older	44.4%
Medicare beneficiaries	71.1%
Medicaid recipients	26.7%

Source: Section C, page 30 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 the applicant’s history of providing services to medically underserved groups and its statement that these groups will continue to have access to their 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.

- (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.

C

The applicant proposes to relocate no more than one dialysis station from FMC Tarboro to be used for home hemodialysis training and support for a total of no more than 2 stations upon project completion.

On page 36, the applicant provides a table of the stations that will be reduced from FMC Tarboro and relocated to Edgecombe Home Dialysis in Edgecombe County in the table below:

<b>FMC Tarboro</b>		
County where the facility is located		Edgecombe
1	Total number of existing, approved, and proposed dialysis stations as of the application deadline	16
2	Number of existing dialysis stations to be reduced, relocated or eliminated in this proposal	1
3	Total number of dialysis stations upon completion of this project and all other projects involving this facility (you should be able to subtract Line 2 from Line 1; if you cannot, explain why not)	15

Note: The applicant received material compliance approval on March 21, 2024, pursuant to CON Project ID# L-12103-21 to develop only 2 of 4 stations pursuant to this project. As a result, the facility is only approved for a total of 16 stations and is currently certified for that amount.

In Section D, pages 36-37, the applicant provides its methodology and assumptions for projecting utilization for FMC Tarboro following, which is summarized below.

The applicant states that FMC Tarboro is currently a 16-station dialysis facility, offering in-center dialysis.

1. The applicant will project growth of the facility census through December 31, 2026, the date the stations are projected to be relocated from FMC Tarboro to Edgecombe Home.
2. The applicant will begin projections using the Edgecombe County facility census as of December 31, 2024. This information was reported on the 2024 ESRD Data Collection form and submitted to Healthcare Planning in February 2025 and is reflected in the Chapter 9: Dialysis Data by County of Patient Origin Report for the Proposed 2026 SMFP.
3. The applicant will project growth of the Edgecombe County patient population using the Edgecombe County 5-Year AACR of 6.7%, as published in the 2025 SMFP.
4. The facility also served a total of four in-center patients residing in Halifax (2), Nash (1), and Pitt (1) County. Halifax, Nash and Pitt County are all contiguous to Edgecombe County. Thus, it is reasonable to conclude that patients residing in these areas would continue dialysis at FMC Tarboro as a function of patient choice. The applicant will not project any growth for this segment of the patient population but will carry these patients forward at appropriate points in time.
5. The station being relocated from FMC Tarboro is projected to be certified at Edgecombe Home Dialysis on December 31, 2026.

Operating Year 1 is the period from January 1 – December 31, 2026.

Operating Year 2 is the period from January 1 – December 31, 2027.

**In-Center Methodology:**

Begin with the Edgecombe County patient population as of December 31, 2024.	59.0
Project the Edgecombe County patient population forward one year to December 31, 2025.	$59.0 \times 1.067 = 63.0$
Add the 4 in-center patients from other counties. This is the projected ending census for Interim Year 1.	$63.0 + 4 = 67.0$
Project the Edgecombe County patient population forward one year to December 31, 2026.	$63.0 \times 1.067 = 67.2$
Add the 4 in-center patients from other counties. This is the projected ending census for Interim Year 2.	$67.2 + 4 = 71.2$
Project the Edgecombe County patient population forward one year to December 31, 2027.	$67.2 \times 1.067 = 71.7$
Add the 4 in-center patients from other counties. <b>This is the projected ending census for Operating Year 1.</b>	$71.2 + 4 = 75.7$
Project the Edgecombe County patient population forward one year to December 31, 2028.	$71.2 \times 1.067 = 76.5$
Add the 4 in-center patients from other counties. <b>This is the projected ending census for Operating Year 2.</b>	$76.5 + 4 = 80.5$

The applicant states that the calculations indicate that FMC Tarboro is projected to have an in-center census of 71.2 in-center patients as of December 31, 2026. Assuming the facility would only have 15 stations, utilization is calculated as follows:

71.2 patients dialyzing on 15 stations = 4.74 patients per station, or 118.62% utilization.

On page 38, the applicant states:

*“Upon completion of the proposed project, and the project to backfill one station at FMC Tarboro, the facility will be certified for 16 stations and will have sufficient capacity to serve the patients who chose to dialyze at this facility, thus this application to relocate station to Edgecombe Home Dialysis will not adversely affect the patients remaining at the FMC Tarboro facility.”*

The information is reasonable and adequately supported because upon completion of the proposed project, and the project to backfill one station at FMC Tarboro, the facility will be certified for 16 stations and will have sufficient capacity to serve the patients who chose to dialyze at this facility, thus this application to relocate station to Edgecombe Home Dialysis will not adversely affect the patients remaining at the FMC Tarboro facility.

### **Access to Medically Underserved Groups**

In Section D, page 38, the applicant states the proposed relocation of an existing station between facilities within the same county will not have any effect on the ability of any members of the above identified groups to have convenient and adequate access to dialysis care in Edgecombe County. The applicant adequately demonstrates that the needs of medically underserved groups will be adequately met following completion of the project based on FMC Tarboro history of providing care of these groups and its statements assuring continued access.

### **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 needs of the population currently using the services to be reduced, eliminated or relocated will be adequately met following project completion for all the reasons described above.
  - The applicant adequately demonstrates that the project will not adversely impact the ability of underserved groups to access these services following project completion for all the reasons described above.
- (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.

### C

The applicant proposes to relocate no more than one dialysis station from FMC Tarboro to be used for home hemodialysis training and support for a total of no more than 2 stations upon project completion.

In Section E, page 40, the applicant states that there were no alternatives to consider because:

- The applicant states that a dialysis station is necessary to provide hemodialysis training services. The applicant states that there are currently three Fresenius Medical Care related facilities with in-center stations operating in Edgecombe County (see Criterion 6). The BMA East Rocky Mount and FMC Tarboro facilities, as well as the FKC Boice-Willis facilities do not have space to accommodate a home training program. Edgecombe Home Dialysis is the only facility in Edgecombe County that offers a home therapy program. The

applicant states it decided not to expend capital for an additional home training program at this time because it is a more costly alternative.

- The applicant states that failure to apply for additional stations leads to higher utilization rates. The applicant believes that this surge in home dialysis patients is a direct result of 1) a national emphasis on home dialysis and 2) an increase in referrals and admissions by the ENA physicians and their commitment to home dialysis because of the improved quality of life that it offers to ESRD patients. The applicant assumes that the ENA physicians will continue to refer more patients to the facility for home dialysis. The relocation of this station will help to address the surge in home dialysis patients and increase access to home hemodialysis training and support services in Edgecombe County.
- The applicant states that if Fresenius Medical Care is to increase access to home hemodialysis within Edgecombe County, the only option is to relocate a station from an existing facility and dedicate that station to providing home hemodialysis training and support services.

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

- The applicant provides reasonable information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

#### 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. Therefore, the application is approved subject to the following conditions:

- 1. FMS ENA Home, LLC, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall relocate no more than one dialysis station from FMC Tarboro to be used for home hemodialysis training and support for a total of two stations at Edgecombe Home Dialysis upon project completion.**
- 3. Progress Reports**
  - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable**

- and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
- b. The certificate holder shall complete all sections of the Progress Report form.**
  - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
  - d. The first progress report shall be due on July 1, 2026.**
- 4. The certificate holder 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 relocate no more than one dialysis station from FMC Tarboro to be used for home hemodialysis training and support for a total of no more than 2 stations upon project completion.

**Capital and Working Capital Costs**

In Section Q, Form F.1a Capital Cost, page 86, the applicant projects the total capital cost of the project, as summarized below.

<b>Capital Cost</b>	<b>Bio-Medical Applications of North Carolina, LLC</b>	<b>Total</b>
Non-Medical Equipment	\$750	\$750
Furniture	\$3,000	\$3,000
<b>Total Capital Cost</b>	<b>\$3,750</b>	<b>\$3,750</b>

In Section Q, page 87, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on furniture estimate includes all necessary furniture for operation of the facility, to include patient chairs, TVs, and office furniture necessary for staff. Non-medical Equipment is primarily comprised of any system necessary for dialysis operations. Other items would include computers and phone systems.

In Section F, the applicant states there will be no start-up costs or initial operating expenses because this is an existing facility that is already operational.

**Availability of Funds**

In Section F, page 43, the applicant will utilize corporate accumulated reserves to fund this project. The applicant is relying upon the corporate accumulated reserves of Fresenius Medical Care Holdings, Inc. to finance this project. In Exhibit F-2, the applicant provides a September 15, 2025 letter signed by the VP Corporate Tax North America for Fresenius Medical Care Holdings, Inc. confirming the proposal capital cost of the project, the availability of sufficient funds for both the capital cost and committing the funds to this project development.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the letter of commitment provided in 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.

<b>Edgecombe Home Dialysis</b>	<b>1<sup>st</sup> Full Fiscal Year CY2027</b>	<b>2<sup>nd</sup> Full Fiscal Year CY2028</b>
Total of Treatments	6,574	6,865
Total Gross Revenues (Charges)	\$41,354,046	\$43,189,044
Total Net Revenue	\$3,051,893	\$3,188,925
Average Net Revenue per Treatments	\$464	\$465
Total Operating Expenses (Costs)	\$1,801,409	\$1,857,965
Average Operating Expense per Treatments	\$274	\$271
<b>Net Income</b>	<b>\$1,250,484</b>	<b>\$1,330,960</b>

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q, pages 89-97. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant states that the treatment revenues are calculated by determining the total number of annual treatments by payor class and determining revenue by payor class.
- 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.

C

The applicant proposes to relocate no more than one dialysis station from FMC Tarboro to be used for home hemodialysis training and support for a total of no more than 2 stations upon project completion.

On page 113, the 2025 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 Edgecombe County. Facilities may serve residents of counties not included in their service area.

According to Table 9A on page 122 of the 2025 SMFP, there are three existing or approved dialysis facilities in Edgecombe County. The applicant states that this project proposes to develop an additional station at a freestanding home training facility.

Facility	Certified Stations 12/31/2023	# of IC Patients 12/31/2023	Utilization Rate 12/31/2023
Edgecombe Home Dialysis	1	4	36
<b>Total</b>	<b>1</b>	<b>4</b>	<b>36</b>

The above table identifies all the existing and approved dialysis facilities in Edgecombe County that provide the same health services proposed in this application. Edgecombe Home Dialysis is the only facility that offers home dialysis services in Edgecombe County.

In Section G, page 49, the applicant explains why it believes its proposal would not result in the necessary duplication of existing or approved dialysis services in Edgecombe County. The applicant states:

*“The applicant is not proposing to develop a new dialysis station with this proposal. The applicant proposes to relocate an existing certified dialysis station from another facility within Edgecombe County. This station is already certified and will not duplicate any existing or approved services.”*

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:

- The proposal would not result in an increase in certified dialysis stations in Edgecombe County.
- The applicant adequately demonstrates that the proposed relocation of the existing certified dialysis station is needed in Edgecombe County.

### **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.

- (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 relocate no more than one dialysis station from FMC Tarboro to be used for home hemodialysis training and support for a total of no more than 2 stations upon project completion.

On Form H referenced in Section Q, page 98, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Current FTE Staff	Projected FTE Staff
	As of 7/18/2025	Interim Full FY 2026
Administrator (FMC Clinic Manager)	0.35	0.35
Home Training Nurses (HTNs)	2.00	2.00
Technicians (PCT)	1.00	1.00
Dietician	0.25	0.25
Social Worker	0.25	0.25
Maintenance	0.25	0.25
Administration/Business Office	0.50	0.50
Other (FMC Director of Operations)	0.25	0.25
Other (FMC Chief Technician)	0.15	0.15
Other (FMC In-Service)	0.10	0.10
<b>TOTAL</b>	<b>5.10</b>	<b>5.10</b>

The assumptions and methodology used to project staffing are provided following Form H in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.4 in Section Q. In Section H, pages 50-51, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

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

- The applicant states, in Form H Assumptions, that the staffing is appropriate for dialysis facility operation.
- The applicant projects sufficient operating expenses for the staff proposed by the applicant.
- The applicant describes the required qualifications for staff, continuing education, and other training programs.

**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 relocate no more than one dialysis station from FMC Tarboro to be used for home hemodialysis training and support for a total of no more than 2 stations upon project completion.

**Ancillary and Support Services**

In Section I, page 52, the applicant identifies the necessary ancillary and support services for the proposed services. In Section I, pages 52-57, 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 because the applicant describes the structure in place at both the corporate level and the facility level for providing the necessary ancillary and support services.

**Coordination**

In Section I, page 57, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit H. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant's parent company, Fresenius Medical Care, has existing relationships with local health care and social service providers.
- The applicant provides a letter from the medical director of the facility attesting to the relationship between the medical director's physician practice and the facility.

**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.

- (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

- (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 proposes to relocate no more than one dialysis station from FMC Tarboro to be used for home hemodialysis training and support for a total of no more than 2 stations upon project completion. In Sections K.1 and K.2, page 60 of the application, the applicant states that no new construction or renovations will be required for the 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 64, the applicant provides the historical payor mix during CY2024 for its existing services at Edgecombe Home Dialysis, as shown in the table below.

Primary Payor Source at Admission	Edgecombe Home Dialysis					
	In-center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-Pay		%			0.1	0.39%
Insurance*		%	2.6	63.76%	6.5	17.97%
Medicare*		%	1.2	29.36%	25.1	69.73%
Medicaid*		%	0.3	6.88%	3.4	9.44%
Other		%			0.9	2.48%
<b>Total</b>		%	<b>4.0</b>	<b>100.00%</b>	<b>36.0</b>	<b>100.00%</b>

In Section L, pages 65-66, the applicant provides the following comparison of the population served.

Edgecombe Home	Last Full FY before Submission of the Application	
	% of Total Patients Served	% of the Population of the Service Area
Female	48.9%	51.9%
Male	51.1%	48.1%
Unknown		
64 and Younger	55.6%	80.2%
65 and Older	44.4%	19.8%
American Indian		1.2%
Asian	2.2%	1.2%
Black or African American	75.6%	42.1%
Native Hawaiian or Pacific Islander		0.1%
White or Caucasian	20.0%	53.4%
Other Race	2.2%	5.4%
Declined/ Unavailable		

FMC Tarboro	Last Full FY before Submission of the Application	
	% of Total Patients Served	% of the Population of the Service Area
Female	46.7%	51.9%
Male	53.3%	48.1%
Unknown		
64 and Younger	83.3%	80.2%
65 and Older	16.7%	19.8%
American Indian		1.2%
Asian		1.2%
Black or African American	78.3%	42.1%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	21.7%	53.4%
Other Race		8.0%
Declined/ Unavailable		

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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 66, the applicant states it has no such obligation under any applicable federal regulations to provide uncompensated care, community service, or access by minorities and persons with disabilities.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is confirming 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 67, 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.

Primary Payor Source at Admission	Edgecombe Home Dialysis Projected Payor Mix during the 2 <sup>nd</sup> Full FY CY 2028					
	In-center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-Pay					0.2	0.39%
Insurance *			3.1	63.76%	7.6	17.97%
Medicare *			1.4	29.36%	29.6	69.73%
Medicaid *			0.3	6.88%	4.0	9.44%
Other					1.1	2.48%
<b>Total</b>			<b>4.9</b>	<b>100.00%</b>	<b>42.5</b>	<b>100.00%</b>

\*Including any managed care plans.

On page 67, the applicant provides the assumptions and methodology it uses 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 because it is based upon the Edgecombe Home Dialysis facility's recent history of actual treatment volumes of the facility.

**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 all the reasons stated above

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

C

In Section L, pages 68-69, the applicant adequately describes the range of means by which patients will have access to the proposed services and provides supporting documentation in Exhibit L-4.

### **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.

- (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 relocate no more than one dialysis station from FMC Tarboro to be used for home hemodialysis training and support for a total of no more than 2 stations upon project completion.

In Section M, page 70, 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. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- The applicant provides documentation for their Invitation to Healthcare Professional Training Program letter expressing their intent to extend their services as a clinical training site for nursing students at a community college in the area.
- The applicant states it often receives requests to utilize the facility for health professional training programs and discusses the options it offers when it receives such an inquiry.

### **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.

C

The applicant proposes to relocate no more than one dialysis station from FMC Tarboro to be used for home hemodialysis training and support for a total of no more than 2 stations upon project completion.

On page 113, the 2025 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 Edgecombe County. Facilities may serve residents of counties not included in their service area.

According to Table 9A on page 122 of the 2025 SMFP, there are three existing or approved dialysis facilities in Edgecombe County. The applicant states that this project proposes to develop an additional station at a freestanding home training facility.

Facility	Certified Stations 12/31/2023	# of IC Patients 12/31/2023	Utilization Rate 12/31/2023
Edgecombe Home Dialysis	1	4	36
<b>Total</b>	<b>1</b>	<b>4</b>	<b>36</b>

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 71, the applicant states:

*“The applicant does not expect this proposal to have any effect on the competitive climate in Edgecombe County. The applicant does not project to serve dialysis patients currently being served by another provider. The projected patient population for the facility begins with the current patient population and growth of that population consistent with the Edgecombe County Five Year Average Annual Change Rate published in the 2025 SMFP. The additional station being requested in this application will ensure that patients choosing to receive home dialysis in the service area will continue to have adequate access to high quality home dialysis care.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 72, the applicant states:

*“This is a proposal to relocate one existing dialysis station from FMC Tarboro to Edgecombe Home Dialysis where the station will be utilized exclusively for home hemodialysis training and support. There are no other options to train patients choosing home hemodialysis in Edgecombe County. The applicant is serving a significant number of dialysis patients residing in Edgecombe County. Approval of this application will allow the facility to continue serving patients of the area in a convenient setting. This is an immediate and significantly positive impact to the patients of the area.”*

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

Regarding the impact of the proposal on quality, in Section N, page 72, 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 B of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 72, 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, or any other factor that would classify a patient as underserved.”*

See also Section L and C of the application and any exhibits.

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, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services and the applicant's record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

### **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 all the reasons 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

The applicant proposes to relocate no more than one dialysis station from FMC Tarboro to be used for home hemodialysis training and support for a total of no more than 2 stations upon project completion.

In Section O, page 74, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents resulting in an Immediate Jeopardy violation that 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 130 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.

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 Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are applicable to this review. The application is conforming to all applicable criteria, as discussed below.

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

**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- Edgecombe Home Dialysis is an existing facility. Therefore, this rule is not applicable to this review.

(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.

(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 training.

(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- The applicant is proposing to relocate one existing dialysis station from FMC Tarboro to Edgecombe Home Dialysis for a total of two dialysis stations .In Section C, page 24, the applicant projects it will train 12 home hemodialysis patients on two stations for an average of six home hemodialysis patients per station per year by the end of the first fiscal year of operation following certification of the facility.

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

-C- In Section C, pages 22-23, the applicant provides the assumptions and methodology used to project utilization of the proposed facility by home hemodialysis patients.