

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: April 8, 2026

Findings Date: April 8, 2026

Project Analyst: Chalice L. Moore

Co-Signer: Gloria C. Hale

Project ID #: P-12729-26

Facility: Carteret County Home

FID #: 260024

County: Carteret

Applicant(s): FMS Carteret County Home, LLC

Project: Develop a new dialysis facility dedicated to home hemodialysis and peritoneal dialysis training and support by relocating no more than two dialysis stations from Crystal Coast Dialysis Unit

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.

C

FMS Carteret County Home, LLC (hereinafter referred to as “the applicant” or Carteret County Home) proposes to develop a new dialysis facility dedicated to home hemodialysis and peritoneal dialysis training and support by relocating no more than two in-center dialysis stations from Crystal Coast-Dialysis Unit to Carteret County Home, which will be adjacent to the existing Crystal Coast Dialysis facility Unit. Carteret Home will be in Suite number 20 and will be exclusively dedicated to home dialysis and peritoneal dialysis 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 2026 State Medical Facilities Plan (SMFP) or offer a new institutional health service for which there are any applicable policies in the 2026 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- (2) Repealed effective July 1, 1987.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 develop a new dialysis facility dedicated to home hemodialysis and peritoneal dialysis training and support by relocating no more than two in-center dialysis stations from Crystal Coast Dialysis.

Patient Origin

On page 107, the 2026 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 Carteret County. Facilities may also serve residents of counties not included in their service area.

The proposed project is for a new facility, therefore there is no historical patient origin data. The following table illustrates the historical patient origin for the existing dialysis stations that will be relocated from Crystal Coast Dialysis Unit to the new proposed facility:

| Crystal Coast Dialysis Unit Last Full FY 01/01/2025 to 12/31/2025 | | |
|----------------------------------------------------------------------------------|------------------------------|---------------|
| County | # of In-Center (IC) Patients | % of Total |
| Carteret | 44.0 | 84.6% |
| Craven | 8.0 | 15.4% |
| Total | 52.0 | 100.0% |

Source: Section C, page 23

The applicant has also provided historical patient origin data for FMC Sea Spray. FMC Sea Spray is currently the only facility that provides training and support services for existing home dialysis patients in Carteret County.

| FMC Sea Spray Historical Patient Origin CY 2025 | | | | | | |
|------------------------------------------------------------|------------------|---------------|------------------|---------------|------------------|---------------|
| County | # of IC Patients | % of Total | # of HH Patients | % of Total | # of PD Patients | % of Total |
| Carteret | 11.0 | 44.0% | 2.0 | 33.3 | 11.0 | 42.3% |
| Craven | | | 2.0 | 33.3 | 3.0 | 11.5% |
| Jones | 3.0 | 12.0% | | | 2.0 | 7.7% |
| Onslow | 11.0 | 44.0% | 2.0 | 33.3 | 10.0 | 38.5% |
| Total | 25.0 | 100.0% | 6.0 | 100.0% | 26.0 | 100.0% |

Source: Section C, page 23

The following table illustrates projected patient origin for the proposed Carteret County Home facility.

| Carteret County Home Patient Origin Second Full FY CY 2029 | | | | |
|---------------------------------------------------------------------------|------------------|---------------|------------------|---------------|
| County | # of HH Patients | % of Total | # of PD Patients | % of Total |
| Carteret | 3.0 | 60.1% | 7.1 | 70.2% |
| Craven | | | 1.0 | 9.9% |
| Onslow | 2.0 | 39.9% | 2.0 | 19.9% |
| Total | 5.0 | 100.0% | 10.1 | 100.0% |

Source: Section C, page 23

In Section C, pages 23-27, the applicant provides the assumptions and methodology used to project patient origin. The applicant’s assumptions are reasonable and adequately supported because the Carteret County population is growing, therefore it is reasonable to conclude that the ESRD population in the county will also continue to grow and will benefit from increased access to home dialysis training and support services.

Analysis of Need

In Section C, pages 28-30, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant gives the following reasons:

- There is an increase in the home dialysis population in North Carolina
- Home dialysis affords the patient maximum flexibility with scheduling treatment at times which are convenient, and in the patient’s residence.
- Carteret County’s population has increased by 5.5% between 2020 and 2024 and in addition, the Chapter 9: Dialysis Data by County of Patient Origin Reports for December 31, 2022, through December 31, 2024, show that the total number of Carteret County ESRD patients has increased by 5.7%, or a 2-Year Compound Annual Growth Rate (CAGR) of 2.8%.

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

- The applicant adequately demonstrates need based on the facility’s projected growth in the home therapy patient population.
- The applicant adequately demonstrates need based on Fresenius Medical Care experiencing a larger number of referrals for home dialysis.

Projected Utilization

Home Methodology:

In Section C, page 27, the applicant provides the projected utilization for Carteret County Home, as shown in the following table:

| | HHD | PD |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------------|
| Begin with the Carteret County patient population who have signed letters of support to transfer their care to the facility upon project completion on December 31, 2027. | 1.0 | 5.0 |
| Project the Carteret County patient population forward one year to December 31, 2028 by using the 0.5% 5-year Average Annual Change Rate (AACR) in the 2026 SMFP for Carteret County | $1.0 \times 0.005 = 1.0$ | $5.0 \times 0.005 = 5.0$ |
| Add the patients projected to convert from ICHD to home dialysis. | $1.0 + 1.0 = 2.0$ | $5.0 + 1.0 = 6.0$ |
| Add the patients from other counties. This is the projected ending census for Operating Year 1. | $2.0 + 2.0 = 4.0$ | $6.0 + 3.0 = 9.0$ |
| Project the Carteret County patient population forward one year to December 31, 2029 using the 0.5% AACR. | $2.0 \times 0.005 = 2.0$ | $6.0 \times 0.005 = 6.1$ |
| Add the patients projected to convert from ICHD to home dialysis. | $2.0 + 1.0 = 3.0$ | $6.1 + 1.0 = 7.1$ |
| Add the patients from other counties. This is the projected ending census for Operating Year 2. | $3.0 + 2.0 = 5.0$ | $7.1 + 3.0 = 10.1$ |

Source: Section C, page 27

Based upon these calculations, the applicant projects to serve the following number of patients for the Operating Years 1 and 2.

| | Operating Year 1 | Operating Year 2 |
|---------------------|-------------------------|-------------------------|
| Home Hemodialysis | 4.0 | 5.0 |
| Peritoneal Dialysis | 5.0 | 10.1 |

In Section C, pages 25-26, and in the Form C Utilization subsection of Section Q, page 90, the applicant provides the assumptions and methodology used to project patient utilization, which are summarized below.

- The applicant begins projections of the future patient population to be served with some of the existing home dialysis patients that are currently being followed by the FMC Sea Spray facility. This facility is currently the only facility in Carteret County that offers home dialysis training and support services.
- The applicant has provided a total of 11 letters of support from existing patients in Exhibit C-3. These letters demonstrate that six existing home dialysis patients residing in Carteret County (one HHD and five PD), one existing home dialysis patient residing in Craven County (PD) and four existing home dialysis patients residing in Onslow County (two HHD and two PD) have expressed an interest in transferring to the new Carteret Home facility.
- The applicant will project growth of the Carteret County patient population using a 0.5% growth rate commensurate with the 5-Year Average Annual Change Rate (5-Year AACR) for Carteret County published in the 2026 SMFP.
- Craven and Onslow County are contiguous to Carteret County; thus, it is not unreasonable for patients who reside in these counties to travel to Carteret County once a month for a follow-up visit as an existing home dialysis patient. The applicant will not project growth of the Craven and Onslow County patient population, but these patients will be added to future projections at specific points of time.
- The applicant projects that at least two ICHD patients at Crystal Coast Dialysis Unit will convert to home dialysis during operating years 1 and 2 of the proposed project (1 HHD and 2 PD). The applicant believes that this is reasonable given the ENA physicians represent one of the largest and oldest nephrology groups practicing in North Carolina, particularly in the eastern part of the state, an increased presence and growth of ESRD patients, and Carteret County home dialysis patient population has grown by a CAGR of 25.8% over the last two years and ENA converts approximately 5% of their ICHD patients to home dialysis year over year.
- The stations being relocated from Crystal Coast Dialysis to the new Carteret County Home facility are projected to be certified on December 31, 2027.
 - Operating Year 1 is the period from January 1 – December 31, 2028.
 - Operating Year 2 is the period from January 1 – December 31, 2029.

Home Hemodialysis and Peritoneal Dialysis Methodology:

In Section C, page 31, the applicant provides the projected utilization for Carteret County home, as shown in the following table:

| | # of Home Hemodialysis Patients Trained * | # of Peritoneal Dialysis Patients Trained * |
|-------------------------------|-------------------------------------------|---------------------------------------------|
| 1st Full FY of Operation 2028 | 12.0 | 24.0 |
| 2nd Full FY of Operation 2029 | 14.0 | 26.0 |

Source: Section C, page 31 * 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.

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

- The applicant bases the projections of the future patient population to be served at the facility based on actual patient census at FMC Sea Spray as of December 31, 2023.
- The applicant projects growth of the Carteret County patient population using a 0.5% growth rate commensurate with the 5-Year Average Annual Change Rate (5-Year AACR) for Carteret County published in the 2026 SMFP.

Access to Medically Underserved Groups

In Section C, pages 32-33, the applicant states:

“The applicant, and its parent organization, Fresenius Medical Care, has a long history of providing dialysis services to the underserved populations of North Carolina. The Form O within Section Q identifies Fresenius Medical Care related dialysis facilities in North Carolina (includes operational or CON approved and at some stage of development). Fresenius Medical Care operates more than 100 dialysis facilities across North Carolina. Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons. It is a corporate policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, or health insurer.”

In Section C, page 33, the applicant provides the estimated percentage of total patients to be served for each medically underserved group during the second full fiscal year, as shown in the following table.

| Medically Underserved Groups | Percentage of Total Patients |
|------------------------------|------------------------------|
| Low-income persons | 32.0% |
| Racial and ethnic minorities | 44.0% |
| Women | 36.0% |
| Persons with Disabilities | 12.0% |
| Persons 65 and older | 48.0% |
| Medicare beneficiaries | 86.0% |
| Medicaid recipients | 26.0% |

Source: Section C, page 33

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.

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 develop a new dialysis facility dedicated to home hemodialysis and peritoneal dialysis training and support by relocating no more than two in-center dialysis stations from Crystal Coast Dialysis Unit to Carteret County Home for a total of no more than two stations upon project completion.

In Section D, page 38, the applicant provides the following tables.

| Crystal Coast Dialysis Unit | | |
|--------------------------------------|------------------------------------------------------------------------------------------------------------------|----------|
| County where the facility is located | | Carteret |
| 1 | Total number of existing, approved, and proposed dialysis stations as of the application deadline | 21 |
| 2 | Number of existing dialysis stations to be reduced, relocated or eliminated in this proposal | 2 |
| 3 | Total number of dialysis stations upon completion of this project and all other projects involving this facility | 19 |

Crystal Coast Dialysis Unit

In Section D, page 40, the applicant explains why it believes the needs of the population presently utilizing the services to be relocated will be adequately met following completion of the project.

“Table 9D: Dialysis Station Need Determination by Facility in the 2026 SMFP does not indicate that Crystal Coast Dialysis Unit is eligible to apply for any additional

dialysis stations because the facility currently has sufficient capacity with the existing stations at the facility and will continue to have sufficient capacity with the remaining number of stations at the facility upon completion of the proposed project.

The applicant intends to apply for additional stations in the future as they are determined to be needed, thus this application will not adversely affect the patients remaining at Crystal Coast Dialysis Unit.”

In Section D, pages 38-40, and in Form Utilization C Section Q, pages 90-91, the applicant provides the in-center projected utilization for Crystal Coast Dialysis Unit, as illustrated in the following table.

| | HHD |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|
| Begin with the Carteret County patient population as of December 31, 2025. | 44.0 |
| Project the Carteret County patient population forward one year to December 31, 2026 using the county's AACR of 0.5% from the 2026 SMFP. | $44.0 \times 0.005 = 44.2$ |
| Add the eight in-center patients from other counties. This is the projected ending census for Interim Year 1. | $44.2 + 8.0 = 52.2$ |
| Project the Carteret County patient population forward one year to December 31, 2027. | $44.2 \times 0.005 = 44.4$ |
| Add the eight in-center patients from other counties. This is the projected ending census for Interim Year 2. | $44.4 + 8.0 = 52.4$ |
| The remaining calculations are for completion of the Form D Utilization only. The information is not relevant for determining conformity with CON Review Criterion 3a. | |
| Project the Carteret County patient population forward one year to December 31, 2028. | $44.4 \times 0.005 = 44.7$ |
| Subtract the two Carteret County ICHD patients projected to convert to home dialysis. | $44.7 - 2.0 = 42.7$ |
| Add the eight in-center patients from other counties. This is the projected ending census for Operating Year 1. | $42.7 + 8.0 = 50.7$ |
| Project the Carteret County patient population forward one year to December 31, 2029. | $42.7 \times 0.005 = 42.9$ |
| Subtract the two Carteret County ICHD patients projected to convert to home dialysis. | $42.9 - 2.0 = 40.9$ |
| Add the eight in-center patients from other counties. This is the projected ending census for Operating Year 2. | $40.9 + 8.0 = 48.9$ |

The calculations indicate that Crystal Coast Dialysis Unit is projected to have an in-center census of 52.4 in-center patients as of December 31, 2027. Assuming the facility would only have 19 stations, utilization is calculated as follows:

52.4 patients dialyzing on 19 stations = 2.76 patients per station per week, or 69.0% utilization.

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

- The applicant begins its calculations for the Crystal Coast Dialysis Unit based on its in-center census of Carteret County patients as of December 31, 2025.
- The applicant projects growth of the Carteret County patient population using the Carteret County 5-Year AACR of 0.5%, as published in the 2026 SMFP.

Access to Medically Underserved Groups

In Section C, page 33, and Section D, page 40, the applicant states:

“...the relocation of two dialysis stations from Crystal Coast Dialysis Unit to Carteret County Home will not have any effect on the ability of any members of the above identified groups to have convenient access to dialysis care. The applicant is proposing to relocate existing stations and services within the same county, and the needs of the population to remain at the facility will be adequately addressed, as described in response to 3.b of this Section.”

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.

The applicant adequately demonstrates that the needs of medically underserved groups that will continue to use dialysis services will be adequately met following completion of the project for the following reasons:

- The applicant provides a statement of its intent to continue serving medically underserved populations.
- The applicant provides a projected estimate of the percentage of patients in medically underserved groups it anticipates serving on page 33.

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.

CA

The applicant proposes to develop a new dialysis facility dedicated to home hemodialysis and peritoneal dialysis training and support by relocating no more than two in-center dialysis stations from Crystal Coast Dialysis Unit to Carteret County Home for a total of no more than two stations upon project completion.

In Section E, page 42, the applicant states that there was no other alternative other than choosing to apply or not apply for the proposed project. The applicant states:

“The applicant truly has only one alternative: apply or not apply.

The applicant seeks to develop this facility to better serve the ESRD patient population of Carteret County, choosing home dialysis. Freestanding home therapy facilities have a specific emphasis on home dialysis patients. The applicant believes that this increased emphasis will result in more patients choosing home dialysis which results in an improved quality of life, quality of care, and patient outcomes by offering a more convenient alternative for dialysis treatment over the traditional in-center model of traveling to an in-center clinic 3 x a week.

BMA and the ENA physicians both recognize the importance of home dialysis and are committed to increasing home therapy penetration in Carteret County, especially given the growth in the Carteret County population, Carteret County ESRD patient population, and the Carteret County home dialysis patient population over the last few years. This growth is attributed to BMA home therapy initiatives and the ENA physicians who have been serving CKD and ESRD patients in Carteret and surrounding counties for many years. The practice brings together the collaborative efforts of a team of very qualified nephrologists who provide care for dialysis patients in eastern North Carolina. The home therapy initiatives described in Section C Question 3 of this application demonstrate our continued emphasis on home therapy as the preferred modality of treatment for our dialysis patients. These initiatives are aligned with the 2019 Executive Order on Advancing American Kidney Health and is strong evidence that home dialysis will continue to grow in the future, that greater capacity for home training

and support is needed, which encourages greater rates of home dialysis to improve the quality of life and care for dialysis patients.”

The applicant adequately demonstrates that there are no alternatives other than applying for the proposed project for the following reasons:

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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 Carteret County Home, LLC. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall develop a new dialysis facility, Carteret County Home, dedicated to home hemodialysis and peritoneal dialysis training and support by relocating no more than two in-center dialysis stations from Crystal Coast Dialysis Unit.**
- 3. The certificate holder shall install plumbing and electrical wiring through the walls for no more than two home hemodialysis stations at Carteret County Home.**
- 4. Upon completion of the proposed project, the certificate holder shall take the necessary steps to decertify two in-center dialysis stations at Crystal Coast Dialysis Unit for a total of no more than 19 in-center stations Crystal Coast Dialysis Unit upon project completion.**
- 5. 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 October 1, 2026.**
 - 6. **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 develop a new dialysis facility dedicated to home hemodialysis and peritoneal dialysis training and support by relocating no more than two in-center dialysis stations from Crystal Coast Dialysis Unit to Carteret County Home for a total of no more than two stations upon project completion.

Capital and Working Capital Costs

On Form F.1a in Section Q, page 92, the applicant projects the total capital cost of the project, as shown in the table below.

| | |
|-----------------------------------|--------------------|
| Construction/Renovation Contracts | \$1,353,263 |
| Architect / Engineering Fees | \$121,794 |
| Non-Medical Equipment | \$23,850 |
| Furniture | \$117,780 |
| Generator | \$63,250 |
| Contingency | \$73,753 |
| Total | \$1,753,690 |

In Section Q, page 93, 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 the following:

- The applicant states that the capital costs for this project were developed by the Fresenius Real Estate and Construction Services (RECS) team. Construction estimates are based upon a national database used by the RECS team.
- The applicant states that Architect and Engineering Fees are estimated at 11% of the proposed construction cost.
- The applicant states that the contingency amount is calculated at 20% of the sum of Construction and Architect / Engineering Fees.
- The applicant identifies the items that are included in each category.

In Section F, pages 45-46, the applicant projects that start-up costs will be \$122,526 and initial operating expenses will be \$570,727 for a total working capital of \$693,253. On pages 46-47, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the following:

- The applicant states that start up costs are comprised of a four week supply of clinical supply/medications and staff salaries.
- The initial operating expenses are calculated as six months of the first-year expenses.

Availability of Funds

In Section F, page 48, the applicant states that the capital cost will be funded by accumulated reserves. Exhibit F-2 contains a letter dated January 15, 2026, from the Vice President of Corporate Tax - North America for Fresenius Medical Care Holdings, Inc. committing \$1,753,690 for the capital cost and any additional working capital necessary for the proposed project. Fresenius Medical Care Holdings, Inc., is the parent company of National Medical Care, Inc., Bio-Medical Applications of North Carolina, Inc. In Exhibit F-2, the applicant includes the Fresenius Medical Care Holdings, Inc. and Subsidiaries Consolidated Financial Statements for quarter three of 2025 which show that the applicant has sufficient funds to support the project.

The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project based on the documentation in Exhibit F.2.

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, page 95, the applicant projects Carteret County Home would be operating in a financial loss position for the first two operating years of the project, as shown in the table below. However, the applicant states, on pages 96-97, that the projected operating loss is solely due to construction cost and that it should be adding capacity and increasing patient census as the opportunity presents itself which should return the facility to a profitable status. Moreover, in Exhibit F-2, the applicant provides a letter from the VP Corporate Tax for Fresenius Medical Care which states that if the facility operates at a loss for the first two operating years, it will absorb the losses. The applicant includes its parent company's recent financial statements in Exhibit F-2 which demonstrate it has the financial means to absorb any losses.

| Carteret County Home | 1st Full FY | 2nd Full FY |
|-----------------------------------------|--------------|--------------|
| | CY2028 | CY2029 |
| Total # of Treatments | 1,778 | 2,079 |
| Total Gross Revenue | \$11,186,782 | \$13,081,575 |
| Total Net Revenue | \$875,506 | \$1,016,214 |
| Average Net Revenue per Treatment | \$492 | \$489 |
| Total Operating Costs | \$1,141,454 | \$1,192,681 |
| Average Operating Expense per Treatment | \$642 | \$57 |
| Net Income | (265,948) | (176,467) |

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 adequately explains the assumptions used to project revenue, such as projected reimbursement rates, and operating costs, such as salaries.
- 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.
- The applicant provides adequate documentation to demonstrate that any losses incurred in operating years one and two will be sufficiently absorbed by the parent company.

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

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

The applicant proposes to develop a new dialysis facility dedicated to home hemodialysis and peritoneal dialysis training and support by relocating no more than two in-center dialysis stations from Crystal Coast Dialysis Unit to Carteret County Home for a total of no more than two stations upon project completion.

On page 107, the 2026 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 Carteret County. Facilities may serve residents of counties not included in their service area.

According to Table 9A on page 114 of the 2026 SMFP, there are 2 existing or approved dialysis facilities in Carteret County as shown in the following table:

| Carteret County | | | |
|-----------------------------|----------------------------------|------------------------------------------|--------------------------------|
| Facility | Certified Stations 12/31/2024 | # of In-Center Patients 12/31/2024 | Utilization Rate 12/31/2024 |
| Crystal Coast Dialysis Unit | 21 | 52 | 61.90% |
| FMC Sea Spray | 11 | 30 | 68.18% |

Source: Table 9A of the 2026 SMFP, page 114.

In Section G, page 51, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved services in Carteret County. The applicant states:

“The applicant is not proposing to develop new dialysis stations with this proposal. Instead, the applicant proposes relocating two existing dialysis stations within Carteret County. As described in Section C of this application, the Carteret County home dialysis patient population has grown, and this growth is projected to continue. The addition of a new facility in the county emphasizing home dialysis training and support services will serve to meet the needs of the county’s growing population, growing ESRD population and growing home dialysis patient population. Because of this growth, there is an increase for home dialysis referrals being made by the admitting nephrologists. The proposed project will relocate existing certified stations within the same county, which is not an unnecessary duplication of the same existing or approved health services located in the service area.”

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 the number of certified dialysis stations in Carteret County.
- The applicant adequately demonstrates that the proposed relocation of existing certified dialysis stations to develop a home dialysis training and support facility is needed in Carteret 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 develop a new dialysis facility dedicated to home hemodialysis and peritoneal dialysis training and support by relocating no more than two in-center dialysis stations from Crystal Coast Dialysis Unit to Carteret County Home for a total of no more than two stations upon project completion.

In Section Q, on Form H, page 103, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

| Position | 1st Full FY | 2nd Full FY |
|------------------------------------|-------------|-------------|
| | CY2028 | CY2029 |
| Administrator (FMC Clinic Manager) | 0.50 | 0.50 |
| Home Training Nurses (RNs) | 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 |
| FMC Director of Operations | 0.25 | 0.25 |
| FMC Chief Technician | 0.25 | 0.25 |
| FMC In-Service | 0.15 | 0.15 |
| Total | 5.40 | 5.40 |

The assumptions and methodology used to project staffing are provided in Section Q, page 104. 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 53-54, 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 projects sufficient operating expenses for the staff proposed by the applicant.

- The applicant describes the methods it uses to attract qualified staff which will enable the facility to maintain staffing levels.
- 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 develop a new dialysis facility dedicated to home hemodialysis and peritoneal dialysis training and support by relocating no more than two in-center dialysis stations from Crystal Coast Dialysis Unit to Carteret County Home for a total of no more than two stations upon project completion.

Ancillary and Support Services

In Section I, page 55, the applicant identifies the necessary ancillary and support services for the proposed services. In Section I, pages 55-60, 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 60, 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 because the applicant has existing relationships with local health care and social service providers in the service area.

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.

C

The applicant proposes to develop a new dialysis facility dedicated to home hemodialysis and peritoneal dialysis training and support by relocating no more than two in-center dialysis stations from Crystal Coast Dialysis to Carteret County Home for a total of no more than two stations upon project completion.

In Section K, page 63, the applicant states that the project involves renovating approximately 3,600 square feet of existing space. Line drawings are provided in Exhibit K-2.

On pages 65-66, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site. Supporting documentation is provided in Exhibit K-4. The site appears to be suitable for the proposed dialysis facility based on the applicant's representations and supporting documentation.

In Section K, pages 63-64, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicant states that finding an existing space which is suitable for renovation and use for a dialysis facility eliminates the cost of building a new space and renovations can be accomplished more cost effectively than building a new structure.
- The applicant states that it will rely upon the extensive experience of Fresenius Medical Care RECS team to ensure project costs are reasonable and accurate.
- The applicant states that the Fresenius RECS team designs facilities with energy efficiency and cost savings in mind.

In Section K, page 64, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services because the applicant states that the cost of development of the dialysis facility will be the responsibility of the applicant and not passed on to the patient. The applicant states this project will not increase costs or charges to the public for the proposed services.

In Section K, pages 64-65, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

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.

- (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 68, the applicant provides the historical payor mix during CY2024 for Crystal Coast Dialysis Unit, the facility from which the existing dialysis stations will be relocated, as shown in the table below.

| Payor Source | Crystal Coast Dialysis Unit, CY2024 | |
|--------------|-------------------------------------|----------------|
| | In-Center Dialysis | |
| | # of Patients | % of Total |
| Self -Pay | 2.6 | 4.98% |
| Insurance | 5.3 | 10.10% |
| Medicare | 40.9 | 78.72% |
| Medicaid | 1.2 | 2.29% |
| Other | 2.0 | 3.91% |
| Total | 52.0 | 100.00% |

In Section L, page 68, the applicant provides the historical payor mix during CY2024 for FMC Sea Spray, the only facility located in Carteret County that currently offers home dialysis and from which patients are projected to transfer to the new Carteret County Home facility, as shown in the table below.

| Payor Source | FMC Sea Spray, CY2024 | | | | | |
|------------------|-----------------------|----------------|-------------------|----------------|---------------------|----------------|
| | In-Center Dialysis | | Home Hemodialysis | | Peritoneal Dialysis | |
| | # of Patients | % of Total | # of Patients | % of Total | # of Patients | % of Total |
| Self-Pay | 0.4 | 1.49% | 0.0 | 0.00% | 0.5 | 1.73% |
| Insurance * | 3.0 | 10.11% | 0.7 | 8.72% | 6.9 | 22.91% |
| Medicare * | 21.9 | 72.85% | 6.4 | 80.41% | 19.3 | 64.35% |
| Medicaid * | 4.6 | 15.47% | 0.7 | 9.07% | 2.2 | 7.23% |
| Other (describe) | 0.0 | 0.08% | 0.1 | 1.80% | 1.1 | 3.78% |
| Total | 30.0 | 100.00% | 8.0 | 100.00% | 30.0 | 100.00% |

In Section L, page 69, the applicant provides the following comparison for Crystal Coast Dialysis Unit.

| Crystal Coast Dialysis Unit | Last Full FY before Submission of the Application | |
|-------------------------------------|---------------------------------------------------|--------------------------------------------------|
| | Percentage of Total Patients Served | Percentage of the Population of the Service Area |
| Female | 36.0% | 51.7% |
| Male | 64.0% | 48.3% |
| Unknown | | |
| 64 and Younger | 52.0% | 87.7% |
| 65 and Older | 48.0% | 12.3% |
| American Indian | 0.0% | 0.7% |
| Asian | 4.0% | 6.7% |
| Black or African-American | 30.0% | 56.6% |
| Native Hawaiian or Pacific Islander | 2.0% | 0.1% |
| White or Caucasian | 60.0% | 43.9% |
| Other Race | 4.0% | 7.9% |
| Declined / Unavailable | 0.0% | 0.0% |

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 70, the applicant states it has no such obligation.

In Section L, page 70, 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 70, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

| Payor Source | Carteret County Home, CY2029 | | | |
|--------------|------------------------------|----------------|---------------------|----------------|
| | Home Hemodialysis | | Peritoneal Dialysis | |
| | # of Patients | % of Total | # of Patients | % of Total |
| Self-Pay | 0.0 | 0.00% | 0.2 | 1.73% |
| Insurance * | 0.4 | 8.72% | 2.3 | 22.91% |
| Medicare * | 4.0 | 80.41% | 6.5 | 64.35% |
| Medicaid * | 0.5 | 9.07% | 0.7 | 7.23% |
| Other ^ | 0.1 | 1.80% | 0.4 | 3.78% |
| Total | 5.0 | 100.00% | 10.1 | 100.00% |

Source: Section L, page 70.

*Includes any managed care plans.

^Other includes all other reimbursement sources, including VA.

As shown in the table above, during the second full fiscal year of operation for home hemodialysis, the applicant projects that 0% of services will be provided to self-pay patients, 80.41% to Medicare patients and 9.07% to Medicaid patients.

As shown in the table above, during the second full fiscal year of operation for peritoneal dialysis, the applicant projects that 1.73% of services will be provided to self-pay patients, 64.35% to Medicare patients and 7.23% to Medicaid patients.

On pages 70-71, 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 states that it relied on the recent performance of FMC Sea Spray to determine the projected home hemodialysis and peritoneal dialysis payor mix for Carteret County Home.
- The applicant states that it calculates payor mix based upon treatment volumes.
- The applicant states that the payor source is determined based upon treatment reimbursement.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 72, 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 a new dialysis facility dedicated to home hemodialysis and peritoneal dialysis training and support by relocating no more than two in-center dialysis stations from Crystal Coast Dialysis Unit to Carteret County Home for a total of no more than two stations upon project completion.

In Section M, page 74, 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.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 applicant's statement and the inclusion of a copy of a letter sent to Carteret Community College encouraging the school to include the dialysis facility in their clinical rotations for nursing students.

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 develop a new dialysis facility dedicated to home hemodialysis and peritoneal dialysis training and support by relocating no more than two in-center dialysis stations from Crystal Coast Dialysis Unit to Carteret County Home for a total of no more than two stations upon project completion.

On page 107, the 2026 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 Carteret County. Facilities may serve residents of counties not included in their service area.

According to Table 9A on page 114 of the 2026 SMFP, there are two existing or approved dialysis facilities in Carteret County as shown in the following table:

| Carteret County | | | |
|-----------------------------|----------------------------------|------------------------------------------|--------------------------------|
| Facility | Certified Stations 12/31/2024 | # of In-Center Patients 12/31/2024 | Utilization Rate 12/31/2024 |
| Crystal Coast Dialysis Unit | 21 | 52 | 61.90% |
| FMC Sea Spray | 11 | 30 | 68.18% |

Source: Table 9A of the 2026 SMFP, page 114.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 75, the applicant states:

“The applicant does not expect this proposal to have any effect on the competitive climate in Carteret 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 as described in Section C of this application. The proposed project will relocate existing stations within Carteret County to 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 75, the applicant states:

*“Fresenius Medical Care-related facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid.... The facility must capitalize upon every opportunity for efficiency. Fresenius Medical Care related facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients.”
... all staff members work toward the clinical and financial success of the facility.”*

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

Regarding the impact of the proposal on quality, in Section N, page 76, 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. Our organizational mission statement captures this sentiment very well:

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

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 76, 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.

Fresenius related facilities in North Carolina have historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender, handicap, age or any other grouping/category or basis for being an underserved person. Low income and medically underinsured persons will continue to have access to all services provided by Fresenius-related facilities.”

See also Sections 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 develop a new dialysis facility dedicated to home hemodialysis and peritoneal dialysis training and support by relocating no more than two in-center dialysis stations from Crystal Coast Dialysis Unit to Carteret County Home for a total of no more than two stations upon project completion.

In Section Q, Form O, pages 105-108, 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 133 of this type of facility located in North Carolina.

In Section O, page 81, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents related to quality of care, including immediate jeopardy, in any of these facilities. After reviewing and considering information provided by the applicant and considering the quality of care provided at all 133 facilities, 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 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- The applicant does not propose to develop a new dialysis facility for in-center hemodialysis services.

(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.*

-C- This proposal is to develop a new dialysis facility dedicated to HHD and PD training and support services by relocating two existing dialysis stations from Crystal Coast Dialysis Unit to Carteret County Home. In Section C, page 35, 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.

(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.*

-NA- The applicant is not proposing to increase the number of home hemodialysis stations in a dialysis facility dedicated to home hemodialysis or peritoneal dialysis training.

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

-C- In Section C, page 35, the applicant provides the assumptions and methodology used to project utilization of the proposed facility by home hemodialysis patients.