

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: April 27, 2022

Findings Date: April 27, 2022

Project Analyst: Gregory F. Yakaboski

Co-Signer: Gloria C. Hale

Project ID #: E-12176-22

Facility: Fresenius Kidney Care North Catawba

FID #: 220064

County: Catawba

Applicant: Bio-Medical Applications of North Carolina, Inc.

Project: Develop a new dialysis facility by relocating no more than eight dialysis stations from FMC Dialysis Services of Hickory and no more than four dialysis stations from FMC of Catawba Valley for a total of no more than 12 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

Bio-Medical Applications of North Carolina, Inc. (hereinafter referred to as “the applicant” or BMA), proposes to develop a new 12-station dialysis facility, Fresenius Kidney Care North Catawba (FKC North Catawba), by relocating no more than eight dialysis stations from FMC Dialysis Services of Hickory (FMC Hickory) and no more than four dialysis stations from FMC of Catawba Valley (FMC Catawba Valley). Both FMC Hickory and FMC Catawba Valley are in Catawba County. The proposed facility, FKC North Catawba will also be in Catawba County. BMA is a wholly owned subsidiary of Fresenius Medical Care Holdings, Inc. (FMC or Fresenius).

FKC North Catawba proposes to provide in-center (IC) dialysis but does not propose to provide either a peritoneal dialysis (PD) program or a home hemodialysis (HH) program.

The applicant does not propose to develop any beds or services, acquire any medical equipment or offer a new institutional health service for which there is a need determination in the 2022 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- (2) Repealed effective July 1, 1987.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 12-station dialysis facility, FKC North Catawba, by relocating no more than eight stations from FMC Hickory and no more than four stations from FMC Catawba Valley.

The following table, summarized from data on page 16 of the application, shows the projected number of stations at FKC North Catawba upon project completion.

| FKC North Catawba | | |
|--------------------------|--|---------------------|
| Stations | Description | Project ID # |
| 0 | Total existing certified stations in the SMFP in effect on the day the review will begin | |
| +12 | Stations to be added as part of this project (develop new 12-station facility) | E-12176-22 |
| 12 | Total stations upon completion of proposed project and previously approved projects | |

The following tables, summarized from information on page 40 of the application, shows the current and projected number of dialysis stations at FMC Hickory and FMC Catawba Valley upon completion of this project.

| FMC Hickory | | |
|--------------------|--|---------------------|
| Stations | Description | Project ID # |
| 33 | Total existing certified stations in the SMFP in effect on the day the review will begin | |
| -8 | Stations to be deleted as part of this project | E-12176-22 |
| 25 | Total stations upon completion of proposed project and previously approved projects | |

| FMC Catawba Valley | | |
|---------------------------|--|---------------------|
| Stations | Description | Project ID # |
| 25 | Total existing certified stations in the SMFP in effect on the day the review will begin | |
| -4 | Stations to be deleted as part of this project | E-12176-22 |
| 21 | Total stations upon completion of proposed project and previously approved projects | |

Patient Origin

On page 115, the 2022 SMFP defines the service area for dialysis stations as “the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell and Yancey counties.” FKC North Catawba will be in Catawba County. Thus, the service area for this application is Catawba County. Facilities may serve residents of counties not included in their service area.

This proposal is to develop FKC North Catawba, a new 12-station dialysis facility in Catawba County; therefore, there is no historical patient origin data. In Section C.2, page 26, the applicant provides the historical (CY2021) patient origin for FMC Hickory and FMC Catawba Valley, the facilities from which the 12 stations are being relocated, as summarized in the following tables.

FMC Hickory

| County | In-Center | | Home Hemodialysis | | Peritoneal Dialysis | |
|---------------|--------------------|-------------------|--------------------------|-------------------|----------------------------|-------------------|
| | IC Patients | % of Total | HH Patients | % of Total | PD Patients | % of Total |
| Catawba | 87 | 87.0% | 0.0 | 0.0% | 0.0 | 0.0% |
| Burke | 6 | 6.0% | 0.0 | 0.0% | 0.0 | 0.0% |
| Caldwell | 4 | 4.0% | 0.0 | 0.0% | 0.0 | 0.0% |
| Alexander | 3 | 3.0% | 0.0 | 0.0% | 0.0 | 0.0% |
| Total | 100 | 100.0% | 0.0 | 0.0% | 0.0 | 0.0% |

FMC Catawba Valley

| County | In-Center | | Home Hemodialysis | | Peritoneal Dialysis | |
|---------------|--------------------|-------------------|--------------------------|-------------------|----------------------------|-------------------|
| | IC Patients | % of Total | HH Patients | % of Total | PD Patients | % of Total |
| Catawba | 85 | 100.0% | 0.0 | 0.0% | 0.0 | 0.0% |
| Total | 85 | 100.0% | 0.0 | 0.0% | 0.0 | 0.0% |

In Section C.3, page 27, the applicant provides the projected IC, PD, and HH patient origin for FKC North Catawba for the second full operating year following project completion (CY2026), as summarized in the following table:

FKC North Catawba

| County | In-Center | | Home Hemodialysis | | Peritoneal Dialysis | |
|--------------|-------------|---------------|-------------------|-------------|---------------------|-------------|
| | IC Patients | % of Total | HH Patients | % of Total | PD Patients | % of Total |
| Catawba | 33.6 | 89.4% | 0.0 | 0.0% | 0 | 0.0% |
| Burke | 3 | 8.0% | 0.0 | 0.0% | 0 | 0.0% |
| Caldwell | 1 | 2.7% | 0.0 | 0.0% | 0 | 0.0% |
| Total | 37.6 | 100.0% | 0.0 | 0.0% | 0 | 0.0% |

In Section C.3, page 27, the applicant provides the assumptions and methodology used to project FKC North Catawba’s patient origin. The applicant’s assumptions are reasonable and adequately supported based on the following:

- The applicant states the patient origin projections are based on the home addresses of the applicant’s in-center patients who have expressed an intention to transfer their care to the proposed facility in Hickory. Copies of the letters are included in Exhibit C-3 of the application.
- The applicant uses the 5.9% Catawba County Five Year Average Annual Change Rate (AACR) as published in the 2022 SMFP to project patient growth for the Catawba County patient population.
- The applicant assumes the four patients from the contiguous counties of Burke and Caldwell will continue to dialyze at the facility and adds the four patients for future projections, with no growth.
- The proposed new stations are projected to be certified as of December 31, 2024.
- Operating Year (OY) 1 is CY2025. OY2 is CY2026.

Analysis of Need

In Section C.4, pages 27-31, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, which are summarized below:

- The applicant identified the existing Catawba County BMA facilities and the residence locations of in-center patients dialyzing at BMA facilities in Catawba County that could be served more conveniently at the proposed FKC North Catawba facility (pages 30-31).
- The applicant obtained letters from 34 existing BMA patients expressing their willingness to transfer their care to the proposed FKC North Catawba facility (page 27). See Exhibit C-3.

The information is reasonable and adequately supported because it is based on letters from 34 existing in-center BMA patients currently served at other Catawba County facilities who have expressed an interest in transferring their care to the proposed FKC North Catawba facility, as documented in Exhibit C-3 of the application.

Projected Utilization

In Section C.3, pages 27-28, the applicant describes its need methodology and assumptions for projected utilization for the proposed facility summarized as follows:

- The applicant states that 34 existing BMA patients have signed letters expressing an interest in transferring their care to the proposed FKC North Catawba facility. The applicant’s projected beginning census on December 31, 2024 is composed of 30 patients from BMA facilities that are residents of Catawba County who have signed letters that state their willingness to transfer their care to the new facility upon certification.
- The applicant uses the 2022 SMFP Catawba County Five Year AACR of 5.9% for Catawba County patient utilization growth.
- The applicant assumes the four patients from the contiguous counties of Burke and Caldwell will continue to dialyze at the facility and adds the four patients for future projections, with no growth.

The table below summarizes the beginning in-center patient census on December 31, 2024 and its growth through the ending patient census on December 31, 2026.

| | |
|---|----------------------------|
| The applicant begins with 30 Catawba County in-center patients as of December 31, 2024. | 30 |
| The applicant projects the Catawba County in-center patients forward one year to December 31, 2025 using the Catawba County Five-Year AACR of 5.9%. | $30 \times 1.059 = 31.8$ |
| The applicant totals the Catawba County projected patients and the four patients from Burke and Caldwell Counties. This is the projected ending census for Operating Year 1 (CY2025) . | $31.8 + 4 = \mathbf{35.8}$ |
| The applicant projects the Catawba County in-center patients forward one year to December 31, 2026 using the Catawba County Five-Year AACR of 5.9%. | $31.8 \times 1.059 = 33.6$ |
| The applicant totals the Catawba County projected patients and the four patients from Burke and Caldwell Counties. This is the projected ending census for Operating Year 2 (CY2026) . | $33.6 + 4 = \mathbf{37.6}$ |

As the table above shows, the applicant projects 35.8 in-center patients by the end of the first operating year, OY1 (CY2025), for a utilization rate of 2.98 patients per station per week or 74.5% (35.8 patients / 12 stations = 2.98 patients per station / 4 = 0.745 or 74.5%). By the end of OY2 (CY2026), the applicant projects 37.6 in-center patients for a utilization rate of 78.25% (37.6 / 12 = 3.13 / 4 = 0.7825 or 78.25%).

The projected utilization of 2.98 patients per station per week for CY2025 satisfies the 2.8 in-center patients per station per week threshold as required by 10A NCAC 14C .2203(b).

Projected utilization is reasonable and adequately supported for the following reasons:

- The applicant bases the beginning in-center patient census on existing BMA patients who have expressed a desire to transfer their care to the proposed facility.
- The applicant projects the growth of the Catawba County patient census using the Catawba County Five Year AACR of 5.9 percent, as reported in the 2022 SMFP.
- The applicant projects no growth from patients who do not reside in Catawba County.

Access to Medically Underserved Groups

In Section C.6, page 34, the applicant discusses access to the facilities' services, stating:

“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 corporate policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, or health insurer.

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.”

On page 35, the applicant provides the estimated percentage for each medically underserved group it will serve during OY2, as shown in the following table.

| Medically Underserved Groups | Percentage of Total Patients |
|-------------------------------------|-------------------------------------|
| Low income persons | 34.3% |
| Racial and ethnic minorities | 51.9% |
| Women | 45.9% |
| Persons with disabilities | 28.7% |
| Persons 65 and older | 71.8% |
| Medicare beneficiaries | 82.9% |
| Medicaid recipients | 37.0% |

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 following:

- The Fresenius corporate policy commits to provide services to all patients referred for ESRD services.
- Fresenius' facilities have historically provided care to all in need of ESRD services, including underserved persons.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

- Information publicly available during the review and used by the Agency

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

- The applicant adequately identifies the population to be served.
 - The applicant adequately explains why the population to be served needs the services proposed in this application.
 - Projected utilization is reasonable and adequately supported.
 - The applicant describes the extent to which all residents, including underserved groups, are likely to have access to the proposed services and adequately supports its assumptions.
- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

C

The applicant proposes to develop a new 12-station dialysis facility, FKC North Catawba, by relocating no more than eight stations from FMC Hickory and no more than four stations from FMC Catawba Valley.

In Section D, pages 40-45, 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.

FMC Hickory

On page 41, the applicant provides a table which shows projected FMC Hickory utilization assuming the relocation of eight stations and 22 in-center patients to the proposed facility, FKC North Catawba, which is summarized below:

| | |
|--|-----------------------------|
| The applicant begins with total Catawba County in-center patients at FMC Hickory as of December 31, 2021. | 82 |
| The applicant projects the Catawba County in-center patients forward one year to December 31, 2022 using the Catawba County Five-Year AACR of 5.9%. | $82 \times 1.059 = 86.8$ |
| The applicant projects the Catawba County in-center patients forward one year to December 31, 2023 using the Catawba County Five-Year AACR of 5.9%. | $86.8 \times 1.059 = 92.0$ |
| The applicant projects the Catawba County in-center patients forward one year to December 31, 2024 using the Catawba County Five-Year AACR of 5.9%. | $92.0 \times 1.059 = 97.4$ |
| Subtract the 22 in-center patients projected to transfer their care to the new FKC North Catawba facility. | $97.4 - 22 = 75.4$ |
| Add the 13 patients from Alexander, Burke and Caldwell Counties that currently utilize FMC Hickory for their care. This is the projected patient census for FMC Hickory for the date the 8 stations are projected to be relocated to FKC North Catawba. | $75.4 + 13 = \mathbf{88.4}$ |

As shown in the table above, FMC Hickory is projected to have a utilization rate of 3.54 patients per station per week or 88.50% ($88.4 \text{ patients} / 25 \text{ stations} = 3.54 / 4 = 0.885$ or 88.50%) following completion of the proposed project on December 31, 2024. The applicant states that the population presently served at FMC Hickory will continue to have their needs adequately met by the remaining and proposed addition of dialysis stations. On pages 42-43, the applicant states:

“BMA notes that Table 9D: Dialysis Station Need Determination by Facility in the 2022 SMFP indicates that FMC Hickory is eligible to apply for up to four additional stations in 2022. BMA intends to apply for four stations to replace four of the eight stations being relocated to FKC North Catawba. FMC Hickory intends to apply for the four stations on November 15, 2022, for the review planned to begin on December 1, 2022.”

FMC Catawba Valley

On page 44, the applicant provides a table which shows projected FMC Catawba Valley utilization assuming the relocation of four stations and six in-center patients to the proposed facility, FKC North Catawba, which is summarized below:

| | |
|---|-----------------------------|
| The applicant begins with total Catawba County in-center patients at FMC Catawba Valley as of December 31, 2021. | 89 |
| The applicant projects the Catawba County in-center patients forward one year to December 31, 2022 using the Catawba County Five-Year AACR of 5.9%. | $89 \times 1.059 = 94.3$ |
| The applicant projects the Catawba County in-center patients forward one year to December 31, 2023 using the Catawba County Five-Year AACR of 5.9%. | $94.3 \times 1.059 = 99.8$ |
| The applicant projects the Catawba County in-center patients forward one year to December 31, 2024 using the Catawba County Five-Year AACR of 5.9%. | $99.8 \times 1.059 = 105.7$ |
| Subtract the 6 in-center Catawba County patients projected to transfer their care to the new FKC North Catawba facility. This is the projected patient census for FMC Catawba Valley for the date the 4 stations are projected to be relocated to FKC North Catawba. | $105.7 - 6 = \mathbf{99.7}$ |

As shown in the table above, FMC Catawba Valley is projected to have a utilization rate of 4.75 patients per station per week or 118.75% ($99.7 \text{ patients} / 21 \text{ stations} = 4.75 / 4 = 1.1875$ or 118.75%) following completion of the proposed project on December 31, 2024. The applicant states that the population presently served at FMC Catawba Valley will continue to have their needs adequately met by the remaining and proposed addition of dialysis stations.

On page 45, the applicant states:

“BMA notes that 2022 SMFP, Table 9D: Dialysis Station Need Determination by Facility indicates that FMC Catawba Valley is eligible to apply for up to five additional stations in 2022. BMA intends to apply for up to five stations to replace the stations being relocated to FKC North Catawba. FMC Catawba Valley intends to apply for additional stations on November 15, 2022, for the review planned to begin on December 1, 2022.”

In Section D, page 45, the applicant states, *“This application to develop FKC North Catawba will not have any effect on the ability of any members of above identified [underserved] groups to have convenient access to dialysis care.”*

Conclusion

The Agency reviewed the:

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

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

- The needs of the population currently using the services to be relocated will be adequately met following project completion.

- The project will not adversely impact the ability of underserved groups to access these services following project completion.
- (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 12-station dialysis facility, FKC North Catawba, by relocating no more than eight stations from FMC Hickory and no more than four stations from FMC Catawba Valley.

In Section E.2, pages 48-49, the applicant describes the alternatives considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the identified need. The alternatives considered were:

- *Maintain the Status Quo* - The applicant states that maintaining the status quo is not an effective alternative because it would not bring dialysis services closer to the patient residences for patients in the Hickory area.
- *Develop a facility with more or less than 12 dialysis stations* – The applicant states that developing a facility with more or less than 12 dialysis stations would be a less effective alternative because the applicant received letters from 34 existing in-center patients for whom the proposed facility would be more convenient, and 12 stations is the right number to meet the identified need.
- *Develop home therapies at the proposed facility* – The applicant states that developing home therapies at the proposed is not the most effective alternative because of the added expense that would be incurred, and the fact that those services are offered at another BMA facility in the Catawba County service area, FMC Hickory Home.

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

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why they believe 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. Bio-Medical Applications of North Carolina, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application and any supplemental responses. If representations conflict, the certificate holder shall materially comply with the last made representation.**
 - 2. The certificate holder shall develop a new 12-station kidney disease treatment center to be known as Fresenius Kidney Care North Catawba by relocating no more than eight in-center and home hemodialysis stations from FMC Dialysis Services of Hickory and no more than four in-center and home hemodialysis stations from FMC of Catawba Valley.**
 - 3. Upon completion of this project, the certificate holder shall take the necessary steps to decertify eight stations at FMC Dialysis Services of Hickory for a total of no more than 25 in-center and home hemodialysis stations upon completion of the project.**
 - 4. Upon completion of this project, the certificate holder shall take the necessary steps to decertify four stations at FMC of Catawba Valley for a total of no more than 21 in-center and home hemodialysis stations upon completion of the project.**
 - 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. Progress reports shall be due on the first day of every fourth month. The first progress report shall be due on July 1, 2022. The second progress report shall be due on October 1, 2022 and so forth.**
 - 6. The certificate holder shall install plumbing and electrical wiring through the walls for no more than 12 in-center and home hemodialysis stations.**
 - 7. 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 12-station dialysis facility, FKC North Catawba, by relocating no more than eight stations from FMC Hickory and no more than four stations from FMC Catawba Valley.

Capital and Working Capital Costs

In Section F.1a, page 50 and Section Q Form F.1a Capital Cost, page 102, the applicant projects the total capital cost of the project, as summarized below.

| | |
|---------------------------|--------------------|
| Site Costs | \$0 |
| Construction Costs | \$1,358,814 |
| Furniture /Fixtures Costs | \$759,738 |
| Total | \$2,118,552 |

In Section Q, pages 102-103, 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 describes each item that makes up the projected capital cost.
- The applicant provided the individual and combined cost of each item that makes up the projected capital cost.

In Section F.3, page 52, the applicant projects that start-up costs will be \$178,906 and initial operating expenses will be \$896,040 for a total working capital of \$1,074,946. [Note: On page 52, there was a typographical error in that the initial operating expenses were listed as \$896,40 rather than \$896,040.] On page 53, 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 provided a detailed breakdown of the start-up costs which included staff salaries and four weeks clinical supply/medications.
- The initial operating expenses were calculated based on six months of the first-year expenses which are provided in detail in the proformas.

Availability of Funds

In Section F, pages 50 and 54, the applicant states that the capital and working capital cost, respectively, will be funded by BMA, as shown in the tables below.

Sources of Capital Financing

| Type | BMA |
|---|--------------------|
| Loans | |
| Cash and Cash Equivalents, Accumulated reserves or OE * | \$2,118,552 |
| Bonds | |
| Other (Specify) | |
| Total Financing | \$2,118,552 |

* OE = Owner's Equity

Sources of Working Capital Financing

| Type | BMA |
|---|--------------------|
| Loans | |
| Cash and Cash Equivalents, Accumulated reserves or OE * | \$1,074,946 |
| Bonds | |
| Other (Specify) | |
| Total Financing | \$1,074,946 |

* OE = Owner's Equity

On pages 51 and 55, the applicant states that “*BMA 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 letter dated January 18, 2022, from Mark Fawcett, the Senior Vice President and Treasurer for Fresenius Medical Care Holdings, parent company for BMA, documenting Mr. Fawcett’s authority to commit the funds for this project, that the funds will be committed to fund the capital and working capital costs of the project and that Fresenius has \$672 million in cash and total assets of over \$2.1 billion as reflected in its 2020 Consolidated Balance Sheet. In supplemental information, the applicant provided a copy of a portion of Fresenius’s 2020 audited Consolidated Balance Sheet documenting over \$446 million in cash and total assets of over \$27 billion.

The applicant adequately demonstrates the availability of funds for the capital and working capital needs of the project.

Financial Feasibility

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

| | 1st Full Fiscal Year (CY2025) | 2nd Full Fiscal Year (CY2026) |
|---|---|---|
| Total Treatments | 5,167 | 5,446 |
| Total Gross Revenues (Charges) | \$32,507,774 | \$34,260,933 |
| Total Net Revenue | \$2,078,083 | \$2,190,155 |
| Average Net Revenue per Treatment | \$402 | \$402 |
| Total Operating Expenses (Costs) | \$1,792,474 | \$1,836,260 |
| Average Operating Expense per Treatment | \$347 | \$337 |
| Net Income | \$285,608 | \$353,895 |

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q of the application. 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.
- Gross revenue of \$6,291 per treatment is based on the base rate for dialysis services. Bad Debt is based on historical performance of FMC Hickory with contractual adjustments based on payor class and modality for each year.
- FTEs and salaries are based on staffing experience and are projected based on average annual salary increases of 2.0%. Payroll taxes and benefits are 36% of the staff expense.
- 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.
- Supplemental information requested by the Agency

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

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

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

C

The applicant proposes to develop a new 12-station dialysis facility, FKC North Catawba, by relocating no more than eight stations from FMC Hickory and no more than four stations from FMC Catawba Valley.

On page 115 the 2022 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell and Yancey counties.*” FKC North Catawba will be in Catawba County. Thus, the service area for this application is Catawba County. Facilities may serve residents of counties not included in their service area.

According to Table 9A, page 122 of the 2022 SMFP, there are four existing or approved dialysis facilities in Catawba County, three of which are owned and operated by Fresenius. Information on these dialysis facilities, from Table 9A of the 2022 SMFP, is provided below:

| Catawba County Dialysis Facilities Certified Stations and Utilization as of December 31, 2020 | | | | |
|--|--------------|-----------------|--------------------------------|--------------------|
| Dialysis Facility | Owner | Location | # of Certified Stations | Utilization |
| Catawba County Dialysis* | DaVita | Hickory | 16 | 64.06% |
| FMC Dialysis Services of Hickory (Fresenius Medical Care of Hickory) | Fresenius | Hickory | 33 | 81.06% |
| FMC of Catawba Valley | Fresenius | Conover | 25 | 90.00% |
| Fresenius Kidney Care Newton** | Fresenius | Newton | 15 | 46.10% |

Source: 2022 SMFP, Table 9A.

* Project ID #E-12044-21 (add no more than 5 stations for 21) is complete and a Certificate of Need was issued with an effective date of July 27, 2021. Services offered December 31, 2021.

**New facility. Services offered May 24, 2019.

In Section G, pages 58-59, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Catawba County. On page 58, the applicant states:

“The applicant is not proposing to develop new dialysis stations by this proposal. The applicant proposes to relocate existing certified dialysis stations within Catawba County. These stations have been previously approved and do not duplicate services.”

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

- The proposal would not result in a surplus of stations or increase an existing surplus of stations in Catawba County.
- The applicant adequately demonstrates that the proposed relocation of the 12 stations for the development of a new facility is needed in addition to the operational facilities in Catawba County.

Conclusion

The Agency reviewed the:

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

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

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

C

The applicant proposes to develop a new 12-station dialysis facility, FKC North Catawba, by relocating no more than eight stations from FMC Hickory and no more than four stations from FMC Catawba Valley.

In Section Q, Form H, the applicant provides the projected staffing in full-time equivalent (FTE) positions for the first and second full operating years of the proposed services, as summarized in the following table.

| POSITION | PROJECTED FTE POSITIONS CY2025 | PROJECTED FTE POSITIONS CY2026 |
|--------------------------------|---|---|
| Administrator | 1.00 | 1.00 |
| Registered Nurse | 2.50 | 2.50 |
| Technicians (PCT) | 4.00 | 4.00 |
| Dietitian | 0.40 | 0.40 |
| Social Worker | 0.40 | 0.40 |
| Maintenance | 0.50 | 0.50 |
| Administrative/Business Office | 0.50 | 0.50 |
| FMC Director of Operations | 0.15 | 0.15 |
| FMC Chief Technician | 0.17 | 0.17 |
| FMC In-service | 0.15 | 0.15 |
| Total | 9.77 | 9.77 |

Source: Section Q, Form H

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in the pro forma financials found in Section Q. In Section H, pages 60-61, 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.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to develop a new 12-station dialysis facility, FKC North Catawba, by relocating no more than eight stations from FMC Hickory and no more than four stations from FMC Catawba Valley.

Ancillary and Support Services

In the table in Section I, page 62, the applicant identifies each ancillary and support service listed in the application as necessary for the proposed services. On pages 62-67, the applicant explains how each ancillary and support service is made available.

The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant currently provides dialysis services at multiple facilities in Catawba County.
- The applicant discusses how it will provide each necessary ancillary and support service at FKC North Catawba.

Coordination

In Section I, page 67, the applicant describes its existing relationships with other local health care and social service providers.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant discusses its relationships with local health care providers.
- The applicant discusses its relationships for lab services and the medical community.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

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

(iv) would be available in a manner which is administratively feasible to the HMO.

NA

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

(11) Repealed effective July 1, 1987.

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

C

The applicant proposes to develop a new 12-station dialysis facility, FKC North Catawba, by relocating no more than eight stations from FMC Hickory and no more than four stations from FMC Catawba Valley.

In Section K.2, page 70, the applicant states that the project will involve renovation of 7,776 square feet of space to be leased in an existing building. The proposed floor plan is provided in Exhibit K-2.

In Section K.3, page 70, the applicant adequately explains how the cost, design and means of construction represent a reasonable alternative for the proposal because the applicant states the building has already been developed and the existing space can be cost-effectively renovated by the applicant's experienced facility and construction services team.

In Section K.3, page 71, 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 developing the new facility is considered the "*necessary part of doing business*" and those costs will be borne by the applicant, and not by the patients who will be served.

In Section K.3, pages 71-72, the applicant identifies applicable energy saving features that will be incorporated into the construction plans.

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, that energy saving features have been incorporated into the construction plans, and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic

minorities, women, and ... 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

The applicant proposes to develop a new 12-station dialysis facility, FKC North Catawba, by relocating no more than eight stations from FMC Hickory and no more than four stations from FMC Catawba Valley.

FKC North Catawba will be a new facility and therefore has no history. In Section L.1, page 75, the applicant provides the historical payor mix for CY2020 for FMC Hickory and FMC Catawba Valley, as shown in the table below.

| Payor Source | FMC Hickory | FMC Catawba Valley |
|---------------------|--------------------|---------------------------|
| Self Pay | 1.5% | 1.0% |
| Insurance | 5.6% | 3.1% |
| Medicare | 81.6% | 84.3% |
| Medicaid | 6.5% | 6.0% |
| Other (VA) | 4.9% | 5.8% |
| Total | 100.0% | 100.0% |

Totals may not sum due to rounding

In Section L.1(a), pages 76-77, the applicant provides comparison of the demographical information on FMC Hickory and FMC Catawba Valley patients and the service area population during the last full operating year, as summarized below.

| | Percentage of Total FMC Hickory Patients Served during the Last Full OY | Percentage of Total FMC Catawba Valley Patients Served during the Last Full OY | Percentage of the Population of the Service Area Where the Stations are Located* |
|-------------------------------------|---|--|--|
| Female | 43.0% | 47.1% | 52.7% |
| Male | 57.0% | 52.9% | 47.3% |
| Unknown | 0.0% | 0.0% | 0.0% |
| 64 and Younger | 30.0% | 29.4% | 83.1% |
| 65 and Older | 70.0% | 70.6% | 16.9% |
| American Indian | 0.0% | 0.0% | 0.0% |
| Asian | 7.0% | 9.4% | 5.1% |
| Black or African American | 47.0% | 47.1% | 12.6% |
| Native Hawaiian or Pacific Islander | 0.0% | 0.0% | 0.0% |
| White or Caucasian | 53.0% | 52.9% | 71.1% |
| Other Race | 0.0% | 0.0% | 12.8% |
| Declined / Unavailable | 0.0% | 0.0% | 0.0% |

* The percentages can be found online using the United States Census Bureau’s QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>. Just enter in the name of the county.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the 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.2(a), page 77, the applicant states that the facility is not obligated to provide uncompensated care, community service or access by minorities and persons with disabilities.

The facility is not an operational facility; therefore, there have been no civil rights access complaints filed against the facility within the last five years.

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.3, page 78, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as summarized in the following table.

**FKC North Catawba
 Projected Payor Mix CY2026**

| Payment Source | In-Center Dialysis | | Home Hemodialysis | | Peritoneal Dialysis | |
|----------------|--------------------|----------------|-------------------|-------------|---------------------|-------------|
| | # of Patients | % of Total | # of Patients | % of Total | # of Patients | % of Total |
| Self-pay | 0.6 | 1.45% | 0.0 | 0.0% | 0.0 | 0.0% |
| Insurance* | 2.1 | 5.55% | 0.0 | 0.0% | 0.0 | 0.0% |
| Medicare* | 31.1 | 81.59% | 0.0 | 0.0% | 0.0 | 0.0% |
| Medicaid* | 2.5 | 6.46% | 0.0 | 0.0% | 0.0 | 0.0% |
| Other (VA) | 1.9 | 4.94% | 0.0 | 0.0% | 0.0 | 0.0% |
| Total | 38.1 | 100.00% | 0.0 | 0.0% | 0.0 | 0.0% |

Totals may not sum due to rounding

*Including any managed care plans

As shown in the table above, during the second full calendar year of operation, the applicant projects that 1.45% of the in-center dialysis patients will be self pay patients, 81.59% will be Medicare patients and 6.46% will be Medicaid patients.

On page 78, the applicant provides the assumptions and methodology used to project payor mix during the first and second full fiscal years of operation following completion of the project. The projected payor mix is reasonable and adequately supported because the applicant's proposed patient payor mix is based on the historical payor mix for FMC Hickory, from which eight of the 12 dialysis stations will be relocated and 22 of the 34 initial projected patient population are transferring their care from FMC Hickory.

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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.5, page 80, 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 12-station dialysis facility, FKC North Catawba, by relocating no more than eight stations from FMC Hickory and no more than four stations from FMC Catawba Valley.

In Section M, page 81, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-1. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes because the applicant provides documentation of its willingness to provide applicable health professional training programs in the area with access to the facility.

Conclusion

The Agency reviewed the:

- Application

- Exhibits to the application

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

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

C

The applicant proposes to develop a new 12-station dialysis facility, FKC North Catawba, by relocating no more than eight stations from FMC Hickory and no more than four stations from FMC Catawba Valley.

On page 115, the 2022 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell and Yancey counties.*” FKC North Catawba will be in Catawba County. Thus, the service area for this application is Catawba County. Facilities may serve residents of counties not included in their service area.

According to Table 9A, page 122 of the 2022 SMFP, there are four existing or approved dialysis facilities in Catawba County, three of which are owned and operated by Fresenius. Information on these dialysis facilities, from Table 9A of the 2022 SMFP, is provided below:

| Catawba County Dialysis Facilities Certified Stations and Utilization as of December 31, 2020 | | | | |
|---|--------------|-----------------|--|--------------------|
| Dialysis Facility | Owner | Location | # of Certified Stations | Utilization |
| Catawba County Dialysis* | DaVita | Hickory | 16 | 64.06% |
| FMC Dialysis Services of Hickory (Fresenius Medical Care of Hickory) | Fresenius | Hickory | 33 | 81.06% |
| FMC of Catawba Valley | Fresenius | Conover | 25 | 90.00% |
| Fresenius Kidney Care Newton** | Fresenius | Newton | 15 | 46.10% |

Source: 2022 SMFP, Table 9A.

* Project ID #E-12044-21 (add no more than 5 stations for 21) is complete and a Certificate of Need was issued with an effective date of July 27, 2021. Services offered December 31, 2021.

**New facility. Services offered May 24, 2019.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 82, the applicant states:

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

Regarding the impact of the proposal on cost effectiveness, in Section N, page 83, the applicant states:

“Approval of this application will allow the facility to continue serving patients of the area in a convenient setting. As a result, these patients will have a shorter commute to and from dialysis treatment. This is an immediate and significantly positive impact to the patients of the area.”

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

Regarding the impact of the proposal on quality, in Section N, page 83, the applicant states:

“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 that 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 83, 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.”

See also Sections C and L 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 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
- Information which was publicly available during the review and used by the Agency

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

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Section Q Form O, 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 over 120 dialysis facilities owned, operated, or managed by a Fresenius Medical Care related entity located in North Carolina.

In Section O, page 88, the applicant states that, during the 18 months immediately preceding the submittal of the application, no Fresenius related facility was found to have had an incident related to quality of care that resulted in a finding of “*Immediate Jeopardy*.” After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all Fresenius facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

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

C

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

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

10A NCAC 14C .2203 PERFORMANCE STANDARDS

(a) An applicant proposing to establish a new kidney disease treatment center or dialysis facility 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 12 months of operation following certification of the facility. An applicant may document the need for less than 10 stations if the application is submitted in response to an adjusted need determination in the State Medical Facilities Plan for less than 10 stations.

-C- In Section C.3, pages 27-28, the applicant projects 36 in-center patients will be served by the proposed facility by the end of the first operating year, CY2025, for a utilization rate of 2.98 patients per station per week or 74.5% (35.8 patients / 12 stations = 2.98 patients per station / 4 = 0.745 or 74.5%). The projected utilization of 2.98 patients per station per week exceeds the 2.8 in-center patients per station per week threshold required by 10A NCAC 14C .2203(a).

(b) An applicant proposing to increase the number of 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 12 months of operation following certification of the additional stations.
- NA- The applicant is proposing to establish a new ESRD facility.
- (c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.
- C- In Section C.3, pages 27-28, and in Section Q, the applicant provides the assumptions and methodology used to project utilization of the facility.