

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: April 19, 2023

Findings Date: April 19, 2023

Project Analyst: Donna Donihi

Co-Signer: Gloria C. Hale

Project ID #: G-12301-22

Facility: Carolina Dialysis - Mebane

FID #: 100545

County: Alamance

Applicant: Carolina Dialysis of Mebane, LLC

Project: Add no more than 2 dialysis stations pursuant to Condition 2 of the facility need methodology for a total of no more than 27 dialysis stations upon completion of this project and Project ID# J-12080-21 (relocate 2 stations)

### REVIEW CRITERIA

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

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

NC

Carolina Dialysis of Mebane, LLC, (hereinafter the “applicant”) proposes to add no more than 2 dialysis stations to Carolina Dialysis-Mebane, in Alamance County, pursuant to Condition 2 of the facility need methodology for a total of no more than 27 dialysis stations upon completion of this project and Project ID# J-12080-21 (relocate 2 stations).

The applicant is a joint venture between Fresenius Medical Care Holdings, Inc. and Carolina Dialysis, LLC, and may at times be referred to as Bio-Medical Applications of North Carolina, Inc, or BMA. BMA is a wholly owned subsidiary of Fresenius Medical Care Holdings, Inc.

CD-Mebane currently provides in-center (IC) dialysis, home hemodialysis (HHD) and peritoneal dialysis (PD).

### **Need Determination (Condition 2)**

Chapter 9 of the 2022 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table 9C, page 139, the county need methodology shows there is not a county need determination for additional dialysis stations in Alamance County.

However, the applicant is eligible to apply for additional dialysis stations in an existing facility pursuant to Condition 2 of the facility need methodology in the 2022 SMFP, if the utilization rate for the facility is at least 75.0% or 3.0 patients per station per week, as stated in Condition 2a. In Table 9A, page 121, the utilization rate reported for the facility is 75.0% or 3.0 patients per station per week, based on 72 in-center dialysis patients and 24 certified dialysis stations ( $72 \text{ patients} / 24 \text{ stations} = 3.0$ ;  $3.0 / 4 = 0.75$ ).

As shown in Table 9D, page 140, based on the facility need methodology for dialysis stations, the potential number of stations needed is up to three additional stations; thus, the applicant is eligible to apply to add up to three stations during the 2022 SMFP review cycle pursuant to Condition 2 of the facility need methodology.

The applicant proposes to add no more than two new dialysis stations to the facility, which is consistent with the 2022 SMFP calculated facility need determination for up to three stations; therefore, the application is consistent with Condition 2 of the facility need determination for dialysis stations.

### **Policies**

There is one policy in the 2022 SMFP that is applicable to this review, *Policy GEN-3: Basic Principles*.

Policy GEN-3, page 30 of the 2022 SMFP, states:

*“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”*

### **Promote Safety and Quality**

The applicant describes how it believes the proposed project will promote safety and quality in Section B, page 21; Section N, page 76; Section O, pages 78-80; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will promote safety and quality.

#### Promote Equitable Access

The applicant describes how it believes the proposed project will promote equitable access in Section B, page 22; Section C, page 34; Section L, pages 68-73; Section N, page 76; and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant's proposal will promote equitable access.

#### Maximize Healthcare Value

The applicant describes how it believes the proposed project will maximize healthcare value in Section B, pages 22-23; Section N, pages 75-76; and referenced exhibits. However, the applicant does not adequately demonstrate how its projected volumes incorporate the concept of maximum healthcare value for resources expended, nor does it adequately demonstrate that the proposed project is the least costly or most effective alternative or that the project will not result in the unnecessary duplication of existing health service capabilities or facilities. See Criteria (3), (4) and (6), which are incorporated herein by reference. Therefore, the applicant does not demonstrate that it will maximize healthcare value for resources expended in meeting the need identified in the 2022 SMFP. Thus, the application is not consistent with Policy GEN-3.

#### Conclusion

The Agency reviewed the:

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

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

- The applicant does not adequately demonstrate how the facility's projected volumes incorporate the concept of maximum value for resources expended in meeting the facility need.
- The applicant does not adequately demonstrate that the proposed project is the least costly or most effective alternative.
- The applicant does not adequately demonstrate that the proposed project will not result in unnecessary duplication of health services in the service area.

- (2) Repealed effective January 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

NC

The applicant proposes to add no more than two dialysis stations at Carolina Dialysis-Mebane pursuant to Condition 2 of the facility need methodology for a total of no more than 27 stations upon completion of this project and Project ID# J-12080-21 (relocate 2 stations).

**Patient Origin**

On page 115, the 2022 SMFP defines the service area for the county need methodology 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-Graham counties and Avery-Mitchell-Yancey counties.*” Carolina Dialysis-Mebane is located in Alamance County. Thus, the service area for this application is Alamance County. Facilities may serve residents of counties not included in their service area.

The applicant provides the following historical in-center (IC) patient, home hemodialysis (HHD), and peritoneal dialysis (PD) patient origin for Carolina Dialysis - Mebane, as summarized below.

County	Historical Carolina Dialysis-Mebane Patient Origin (1/1/2021-12/31/2021)					
	# of IC Patients	% of Total	# of HHD Patients	% of Total	# of PD Patients	% of Total
Alamance	52	71.2%	3.0	60%	4.0	57.1%
Durham	-	-	-	-	1.0	14.3%
Orange	20	27.4%	-	-	1.0	14.3%
Guilford	1	1.4%	1.0	20%	1.0	14.3%
Person	-	-	1.0	20%	-	-
<b>Total</b>	<b>73</b>	<b>100%</b>	<b>5.0</b>	<b>100%</b>	<b>7.0</b>	<b>100%</b>

Source: Section C.2, page 25.

The following table illustrates the projected IC, HHD, and PD patient origin at Carolina Dialysis - Mebane in the second full fiscal year of operation (CY2025).

County	Carolina Dialysis-Mebane Patient Origin 2nd Operating Year (1/1/2025-12/31/2025)					
	# IC Patients	% of Total	# of HHD Patients	% of Total	# of PD Patients	% of Total
Alamance	54.1	68.6%	3.1	75.7%	4.2	58.1%
Durham	-	-	-	-	1.0	14.0%
Orange	23.8	30.1%	-	-	1.0	14.0%
Guilford	1.0	1.3%	1.0	24.3%	1.0	14.0%
<b>Total</b>	<b>78.9</b>	<b>100%</b>	<b>4.1</b>	<b>100%</b>	<b>7.2</b>	<b>100%</b>

Source: Section C.3, page 26

In Section C, pages 26-27, and Section Q, pages 84-90, the applicant provides the assumptions and methodology used to project its patient origin and its projected utilization as follows:

- The applicant states projections are based on the historical patient origin (CY2021) and begins with the facility census as of December 31, 2021, as reported in the 2021 ESRD Data Collection Form submitted to the Agency in May 2022.
- The applicant grows the 52 IC Alamance County patient census by 1.0%, the Five-Year Average Annual Change Rate (AACR) for Alamance County per the 2022 SMFP.
- The applicant grows the 20 IC Orange County patient census by 4.4%, the Five-Year AACR for Orange County per the 2022 SMFP.
- The applicant adds the one IC patient residing in Guilford County, a contiguous county, and assumes the patient will continue to dialyze at Carolina Dialysis-Mebane.
- The applicant grows the 3 HHD Alamance County patient census by 1.0%, the Five-Year AACR for Alamance County per the 2022 SMFP.
- The applicant assumes the one HHD patient from Guilford County, as of December 31, 2021, residing in a contiguous county, will continue to dialyze at Carolina Dialysis - Mebane by choice but does not project any growth in that patient population. That patient is added to projections of future patient populations at the appropriate time.
- The one HHD patient residing in Person County is no longer receiving treatment at Carolina Dialysis-Mebane and will not be carried forward for projections.
- The applicant assumes the three PD patients from Durham, Orange and Guilford counties will continue to dialyze at Carolina Dialysis - Mebane by choice but does not project any growth in those patient populations, adding them to projections of future patient populations at the appropriate time.
- The proposed new stations are projected to be certified as of December 31, 2023.
- Operating Year (OY) 1 is the period from January 1-December 31, 2024.

- Operating Year 2 is the period from January 1-December 31, 2025.

However, the applicant's assumptions for projecting patient origin are not reasonable or adequately supported because the patient origin the applicant uses in its historical utilization to project future utilization for IC and PD patients differs from the patient origin the applicant reported on its ESRD Data Collection Form for the year ending December 31, 2021.

### **Analysis of Need**

In Section C, page 31, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

*“The need that this population has for the proposed services is a function of the individual patient need for dialysis care and treatment. This question specifically addresses the need that the population to be served has for the proposed project. The applicant has identified the population to be served as 77.3 in-center dialysis patients dialyzing with the facility as of the end of the first Operating Year of the project. This equates to a utilization rate of 71.61%, or 2.86 patients per station and exceeds the minimum required by the performance standard.”*

- The applicant demonstrates eligibility to add dialysis stations to its facility under Condition 2 of the facility need methodology, as stated in the 2022 SMFP. The discussion regarding need methodology found in Criterion (1) is incorporated herein by reference.
- The applicant grows the IC Alamance County patient census by 1.0%, the Five-Year AACR for Alamance County per the 2022 SMFP.
- The applicant grows the IC Orange County patient census by 4.4%, the Five-Year AACR for Orange County per the 2022 SMFP.
- The applicant assumes the one in-center patient residing in a surrounding county will continue to dialyze at Carolina Dialysis Center-Mebane by choice but does not project any growth in that patient population and adds this patient to projections of future patient populations at the appropriate time.
- The applicant grows the HHD and PD Alamance County patient census by 1.0%, the Five-Year AACR for Alamance County per the 2022 SMFP.
- The one Person County HHD patient who received dialysis treatments in CY2021 at Carolina Dialysis-Mebane is no longer a patient at the facility and is not counted in future patient population growth projections.
- Then applicant states that the facility will need the additional stations to accommodate projected growth in the patient population.

However, the information is not reasonable or adequately supported because the applicant's beginning census and some of its patient origins it uses to begin its calculations to project need do not match the data it reported to the Agency in its ESRD

Data Collection Form for Carolina Dialysis – Mebane for the year ending December 31, 2021.

**Projected Utilization**

In Section Q, Form C, page 84, the applicant provides the projected utilization, as illustrated in the following table.

Utilization	Last Full FY CY 2020	Interim CY 2022	Interim CY 2023	1st Full FY CY 2024	2 <sup>nd</sup> Full FY CY 2025
<b>In-Center Patients</b>					
# of Patients at the Beginning of the Year	72	73	74	76	77
# of Patients at the End of the Year	73	74	76	77	79
Average # of Patients during the Year	73	74	75	77	78
# of Treatments / Patient / Year	148	148	148	148	148
<b>Total # of Treatments</b>	<b>10,218</b>	<b>10,908</b>	<b>11,335</b>	<b>11,335</b>	<b>11,559</b>
<b>Home Hemodialysis Patients</b>					
# of Patients at the Beginning of the Year	4	5	4	4	4
# of Patients at the End of the Year	5	4	4	4	4
Average # of Patients during the Year	5	5	4	4	4
# of Treatments / Patient / Year	148	148	148	148	148
<b>Total # of Treatments</b>	<b>978</b>	<b>668</b>	<b>599</b>	<b>603</b>	<b>605</b>
<b>Peritoneal Dialysis Patients</b>					
# of Patients at the Beginning of the Year	9	7	7	7	7
# of Patients at the End of the Year	7	7	7	7	7
Average # of Patients during the Year	8	7	7	7	7
# of Treatments / Patient / Year	148	148	148	148	148
<b>Total # of Treatments</b>	<b>1,120</b>	<b>1,039</b>	<b>1,045</b>	<b>1,051</b>	<b>1,057</b>
<b>Total Patients</b>					
# of Patients at the Beginning of the Year	85	85	85	87	89
# of Patients at the End of the Year	85	85	87	89	90
Average # of Patients during the Year	85	85	86	88	89
# of Treatments / Patient / Year	148	148	148	148	148
<b>Total # of Treatments</b>	<b>12,316</b>	<b>12,615</b>	<b>12,762</b>	<b>12,989</b>	<b>13,222</b>

Source: Section Q, page 84



In Section Q, Form C, page 85, the applicant provides the assumptions and methodology used to project in-center utilization, as summarized below.

- The 2022 SMFP indicates Carolina Dialysis-Mebane qualifies under Condition 2 of the facility need methodology for up to 3 additional dialysis stations.
- The first full fiscal year of operation is CY2024, and the second full fiscal year of operation is CY2025.
- Projections begin with the facility census as of December 31, 2021, as reported in the 2022 SMFP.
- The applicant grows the Alamance County patient census by 1.0% and the Orange County patient census by 4.4%, annually, which are respective 5-year AACRs for those counties as found in the 2022 SMFP.
- The applicant assumes the facility will continue to serve the one in-center patient residing in Guilford County but does not project any growth in that patient population.
- The stations are projected to be certified as of December 31, 2023.

The applicant provides a table in Section C, pages 27-28, illustrating the application of its assumptions and methodology.

<b>In-Center Methodology</b>	
Begin with the Alamance County patient census as of December 31, 2021.	52
Project the Alamance County patient census forward one year to December 31, 2022, using the Five-Year AACR for Alamance County of 1%.	$52 \times 1.010 = 52.5$
Project the Orange County patient population forward one year to December 31, 2022, using the Five-Year AACR for Orange County of 4.4%.	$20 \times 1.044 = 20.9$
Add patient from Guilford County. This is the projected ending census for Interim Year 1.	$52.5 + 20.9 + 1 = 74.4$
Project the Alamance County patient census forward one year to December 31, 2023, using the Five-Year AACR.	$52.5 \times 1.010 = 53.0$
Project the Orange County patient population forward one year to December 31, 2023, using the Five-Year AACR.	$20.9 \times 1.044 = 21.8$
Add patient from Guilford County. This is the projected ending census for Interim Year 2.	$53.0 + 21.8 + 1 = 75.8$
Project the Alamance County patient population forward one year to December 31, 2024, using the Five-Year AACR.	$53.0 \times 1.010 = 53.6$
Project the Orange County patient population forward one year to December 31, 2024, using the Five-Year AACR.	$21.8 \times 1.044 = 22.8$
Add patient from Guilford County. <b>This is the projected ending census for Operating Year 1.</b>	$53.6 + 22.8 + 1 = 77.3$
Project the Alamance County patient population forward one year to December 31, 2025, using the Five-Year AACR.	$53.6 \times 1.010 = 54.1$
Project the Orange County patient population forward one year to December 31, 2025, using the Five-Year AACR.	$22.8 \times 1.044 = 23.8$
Add patient from Guilford County. <b>This is the projected ending census for Operating Year 2.</b>	$54.1 + 23.8 + 1 = 78.9$

Source: Section C, pages 27-28. Totals may not sum due to rounding.

As shown in the table above, the applicant projects Carolina Dialysis - Mebane will serve 77.3 in-center patients by the end of the first full fiscal year of operation, for a utilization rate of 2.86 patients per station per week or 71.6% ( $77.3 \text{ patients} / 27 \text{ stations} = 2.86 \text{ patients per station per week} / 4 = 0.7157$ ). By the end of OY2 (December 31, 2025), the applicant projects the facility will have 78.9 in-center patients dialyzing at the center for a utilization rate of 73.06% ( $78.9 / 27 = 2.92 / 4 = 0.7306$ ). Projected utilization must exceed 2.8 in-center patients per station per week for the first year following completion of the project, as required by 10A NCAC 14C .2203(b).

However, projected utilization for IC patients is not reasonable and adequately supported because the applicant's patient origin and patient census as of December 31, 2021 differs from what the applicant reported in its ESRD Data Collection Form submitted to the Agency for the year ending December 31, 2021. The differences include: the number of Alamance and Orange counties' patients, no patients from Guilford County, one patient from Durham County, and 12 patients from Graham County. The numbers of patients from each of these counties, as reported in the facility's ESRD Data Collection Form submitted to the Agency for the year ending December 31, 2021, are not used in the applicant's calculations above. Therefore, the assumptions and methodology are unsupported.

#### Home Hemodialysis (HHD) and Peritoneal Dialysis (PD)

In Section C pages 28-30, the applicant provides the assumptions and methodology used to project HHD and PD utilization, as summarized below.

- Projections begin with the ending census as of December 31, 2021, which was provided to DSHR in May 2022.
- The first full fiscal year of operation is CY2024, and the second full fiscal year of operation is CY2025.
- Projections begin with the facility census as of December 31, 2021, as reported in the 2022 SMFP.
- The applicant grows the Alamance County patient census by 1.0% annually, which is the 5-year AACR for Alamance County as found in the 2022 SMFP.
- The applicant states that there are two HHD patients from Guilford and Person counties, but it assumes the facility will continue to serve only the HHD patient residing in Guilford County and three PD patients residing in Guilford, Orange and Durham counties, but does not project any growth in those patient populations.

#### HHD Projected Utilization

In Section C, page 28, and the Form C Utilization subsection of Section Q, the applicant provides the calculations used to project the HHD patient census for OY1 and OY2, as summarized in the table below.

<b>Home Hemodialysis Methodology</b>	
Begin with the Alamance County patient population as of December 31, 2021.	3
Project the Alamance County patient census forward one year to December 31, 2022, using the Five-Year AACR.	$3 \times 1.010 = 3.0$
Add the one patient from another county. This is the projected ending census for Interim Year 1.	$3.0 + 1 = 4$
Project the Alamance County patient population forward one year to December 31, 2023, using the Five-Year AACR.	$3.0 \times 1.010 = 3.1$
Add one patient from another county. This is the projected interim year census for Interim year 2.	$3.1 + 1 = 4.1$
Project the Alamance County patient population forward one year to December 31, 2024, using the Five-Year AACR.	$3.1 \times 1.010 = 3.1$
Add one patient from another county. <b>This is the projected ending census for Operating Year 1.</b>	$3.1 + 1 = 4.1$
Project the Alamance County patient population forward one year to December 31, 2025, using the Five-Year AACR.	$3.1 \times 1.010 = 3.1$
Add one patient from other counties. <b>This is the projected ending census for Operating Year 2.</b>	$3.1 + 1 = 4.1$

Source: Section C, pages 28-29

The applicant states that at the end of FY1 (CY2024) the facility is projected to serve 4.1 home hemodialysis patients and at the end of FY2 (CY2025) the facility is projected to serve 4.1 home hemodialysis patients.

Projected utilization of HHD patients at Carolina Dialysis – Mebane is reasonable and adequately supported for the following reasons:

- The applicant projects growth of the Alamance County HHD patients based on the Five-Year AACR for Alamance County.

- The applicant adds the one HHD patient from outside the county at the appropriate times in its calculations and projects no growth for that population.

PD Projected Utilization

In Section C, page 29-30, and the Form C Utilization subsection of Section Q, page 89, the applicant provides the calculations used to project the PD patient census for OY1 and OY2, as summarized in the table below.

Begin with the Alamance County patient population as of December 31, 2021.	4
Project the Alamance County patient population forward one year to December 31, 2022, using the Five-Year AACR.	$4 \times 1.010 = 4.0$
Add 3 patients from other counties. This is the projected ending census for Interim Year 1.	$4.0 + 3 = 7$
Project the Alamance County patient population forward one year to December 31, 2023, using the Five-Year AACR.	$4.0 \times 1.010 = 4.1$
Add 3 patients from other counties. <b>This is the projected ending census for Interim Year 2.</b>	$4.1 + 3 = 7.1$
Project the Alamance County patient population forward one year to December 31, 2024, using the Five-Year AACR.	$4.1 \times 1.010 = 4.1$
Add 3 patients from other counties. <b>This is the projected ending census for Operating Year 1.</b>	$4.1 + 3 = 7.1$
Project the Alamance County patient population forward one year to December 31, 2025, using the Five-Year AACR.	$4.1 \times 1.010 = 4.2$
Add 3 patients from other counties. <b>This is the projected ending census for Operating Year 2.</b>	$4.2 + 3 = 7.2$

Source: Section C, pages, 29-30. Totals may not sum due to rounding.

On pages 29-30 and Section Q page 89, the applicant projects that on December 31, 2024, Carolina Dialysis - Mebane will serve 7.1 PD patients by the end of the first full fiscal year of operation. By the end of OY2 (December 31, 2025), the applicant projects the facility will have 7.2 PD patients.

However, projected utilization is not reasonable and adequately supported based on the following:

- The applicant’s beginning PD facility census used in its calculations does not match the PD census reported on its ESRD Data Collection Form for the year ending December 31, 2021. The applicant begins its calculations with four PD patients from Alamance County, however the applicant’s ESRD Data Collection Form for the year ending December 31, 2021 shows there were five PD patients from Alamance County.
- The applicant states that, on December 31, 2021, its PD patient census included three patients from Guilford, Durham and Orange counties who received services at the facility as a function of patient choice and will continue to dialyze at Carolina Dialysis - Mebane. However, the applicant’s ESRD Data Collection Form for the year ending December 31, 2021 shows there were three patients from Durham, Orange and Randolph counties, and none from Guilford 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 34, 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	21.4%
Racial and ethnic minorities	67.5%
Women	45.8%
Persons with disabilities	75.9%
Persons 65 and older	60.2%
Medicare beneficiaries	36.1%
Medicaid recipients	24.1%

Source: Section C, page 34

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:

- 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 not 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, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

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

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

NC

The applicant proposes to add no more than two dialysis stations at Carolina Dialysis-Mebane pursuant to Condition 2 of the facility need methodology for a total of no more than 27 stations upon completion of this project and Project ID# J-12080-21 (relocate 2 stations).

In Section E, page 43, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the status quo – The applicant states that failure to apply for additional stations would result in higher utilization rates and potentially interrupt patient care by the end of the first operating year. Therefore, the applicant states this alternative is not the most effective alternative.
- Add fewer stations – The applicant states that this alternative would also result in higher utilization rates; therefore, the applicant determined that this was not the most effective alternative.
- Add more stations - The applicant states this is not cost effective as the applicant does not have space to add more stations.

Based on the explanations above, the applicant states that its proposal is the most effective alternative.

However, the applicant does not adequately demonstrate that the alternative proposed in this application is the most effective alternative to meet the need because the application is not conforming or conditionally conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be an effective alternative to meet the need.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application



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

- (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.

NC

The applicant proposes to add no more than two dialysis stations at Carolina Dialysis-Mebane pursuant to Condition 2 of the facility need methodology for a total of no more than 27 stations upon completion of this project and Project ID# J-12080-21 (relocate 2 stations).

**Capital and Working Capital Costs**

In Section F.1, page 45, and Section F.3, page 47, the applicant states it will not incur any capital or working capital costs for this project.

**Financial Feasibility**

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

<b>Carolina Dialysis - Mebane</b>	<b>1<sup>st</sup> Full FY CY2024</b>	<b>2<sup>nd</sup> Full FY CY2025</b>
Total Treatments	12,989	13,222
Total Gross Revenue (charges)	\$81,715,296	\$83,176,755
Total Net Revenue	\$4,488,740	\$4,567,011
Average Net Revenue per Treatment	\$346	\$345
Total Operating Expenses (costs)	\$3,813,604	\$3,876,286
Average Operating Expense per Treatment	\$294	\$293
Net Income	\$675,136	\$690,725

Source: Section Q, page 94

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q of the application. However, the applicant does not

adequately demonstrate that the financial feasibility of the proposal is reasonable and adequately supported because projected utilization is not based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference. Therefore, projected revenues and operating expenses, which are based in part on projected utilization, are also questionable.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is not conforming to this criterion because the applicant does not adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.

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

NC

The applicant proposes to add no more than two dialysis stations at Carolina Dialysis-Mebane pursuant to Condition 2 of the facility need methodology for a total of no more than 27 stations upon completion of this project and Project ID# J-12080-21 (relocate 2 stations).

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-Graham counties and Avery-Mitchell-Yancey counties.*” Carolina Dialysis-Mebane is located in Alamance County. Thus, the service area for this application is Alamance County. Facilities may serve residents of counties not included in their service area.

**Alamance County Dialysis Facilities**

<b>Dialysis Facility</b>	<b>Certified Stations 12/31/2020</b>	<b>In-Center Patients 12/31/2020</b>	<b>Utilization Percent 12/31/2020</b>
Alamance County Dialysis	13	42	80.77%
BMA of Burlington	45	94	52.22%
Burlington Dialysis	16	71	110.94%
Carolina Dialysis of Mebane	24	72	75.00%
Glen Raven Dialysis	14	27	48.21%
Mebane Dialysis	10	35	87.50%
North Burlington Dialysis	18	57	79.17%
Fresenius Medical Care of Alexander County	13	49	94.23%

Source: 2022 SMFP, Table 9A, page 121

In Section G, pages 51-52, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Alamance County. The applicant states:

*“It is not uncommon for a facility to have lower utilization while another facility in the same county is well utilized. While some capacity does exist at BMA of Burlington, this facility is strategically located in Burlington to serve other patients of the county in that area. It is much more convenient for the patients to choose dialysis at the facility closest to their residence location as opposed to traveling further for the same dialysis care and treatment.”*

However, the applicant does not adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- The applicant did not adequately demonstrate the need it has for the proposed project or that its projected utilization is reasonable and adequately supported. The discussion regarding analysis of need including projected utilization found in Criterion (3) is incorporated herein by reference.
- The applicant did not demonstrate that its application was conforming with all applicable statutory and regulatory criteria and standards.
- The applicant did not adequately demonstrate that the proposed addition of two stations is needed in addition to the existing and approved dialysis stations in Alamance 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 not conforming to this criterion for all the reasons described above.

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

### C

The applicant proposes to add no more than two dialysis stations at Carolina Dialysis-Mebane pursuant to Condition 2 of the facility need methodology for a total of no more than 27 stations upon completion of this project and Project ID# J-12080-21 (relocate 2 stations).

In Section Q, Form H, the applicant provides current and projected full-time equivalent (FTE) positions for the Carolina Dialysis - Mebane facility, as summarized in the following table:

POSITION	# FTE Positions 2/17/2022	# FTE POSITIONS OY1 2024	# FTE POSITIONS OY2 2025
Administrator	1.00	1.00	1.00
RN	2.50	4.50	4.50
Home Training Nurse	1.00	1.00	1.00
PCT Technician	8.00	8.00	8.00
Dietician	1.00	1.00	1.00
Social Worker	1.00	1.00	1.00
Maintenance	1.00	1.00	1.00
Administration/Business Office	1.00	1.00	1.00
FMC Director of Operations	.17	.17	.17
Chief Technician	.17	.17	.17
FMC In-Service	.17	.17	.17
<b>Total</b>	<b>17.01</b>	<b>19.01</b>	<b>19.01</b>

Source: Section Q Form H, page 102

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.4. In Sections H.2 and H.3, 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 facility is an existing facility and the applicant bases its staffing on its historical experience providing dialysis services at the facility.
- The applicant has existing policies in regard to recruitment, training and continuing education.

**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 add no more than two dialysis stations at Carolina Dialysis-Mebane pursuant to Condition 2 of the facility need methodology for a total of no more than 27 stations upon completion of this project and Project ID# J-12080-21 (relocate 2 stations).

#### **Ancillary and Support Services**

In the table in Section I, page 55, the applicant identifies each ancillary and support service listed in the application as necessary for the proposed services. On pages 55-60, the applicant explains how each ancillary and support service is and will be 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 Carolina Dialysis - Mebane.
- The applicant discusses how it provides each necessary ancillary and support service at Carolina Dialysis - Mebane.

#### **Coordination**

In Section I, page 60, the applicant describes its existing relationships with other local health care and social service providers and provides supporting documentation in Exhibit H.4. 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 with local social service providers.

#### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

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

NA

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

- (11) Repealed effective January 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing

health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

The applicant states it does not propose to construct any new space or renovate any existing space. Therefore, Criterion (12) is not applicable to this review.

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

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

C

In Section L, page 68, the applicant provides the historical payor mix during CY2021 for the proposed services, as shown in the table below.

Payor Category	In-Center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-Pay	2.9	3.94%	-	-	-	-
Insurance *	6.1	8.47%	1.5	30.66%	1.9	27.24%
Medicare *	54.5	75.21%	2.8	56.65%	4.8	69.15%
Medicaid *	7.0	9.61%	0.6	12.69%	0.3	3.61%
Other (VA and Misc.)	2.0	2.78%	-	-	-	-
Total	73.0	100.00%	5.0	100.00%	7.0	100.00%

Source: Section L, page 68



In Section L, page 69, the applicant provides the following comparison.

<b>Carolina Dialysis - Mebane</b>	<b>Percentage of Total Patients Served by the Facility or Campus during the Last Full FY, CY2020</b>	<b>Percentage of the Population of the Service Area</b>
Female	45.8%	56.0%
Male	54.2%	44.0%
Unknown	-	-
64 and Younger	39.8%	87.9%
65 and Older	60.2%	12.1%
American Indian	0.0%	0.2%
Asian	0.0%	2.1%
Black or African American	54.2%	26.3%
Native Hawaiian or Pacific Islander	0.0%	-
White or Caucasian	32.5%	64.7%
Other Race	0.0%	11.6%
Declined / Unavailable	0.0%	0.0%

Source: Section L, page 69

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 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 that Carolina Dialysis - Mebane is not obligated under any applicable federal regulations to provide uncompensated care, community service, or access by minorities and persons with disabilities.

In Section L, page 70, the applicant states that during the last 18 months no patient civil rights access complaints have been filed against Carolina Dialysis - Mebane.

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(a), page 71, 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 summarized in the table below.

Carolina Dialysis – Mebane Projected Payor Mix 01/01/2025-12/31/2025						
Payment Source	In-Center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-Pay	3.1	3.94%	0.0	0.00%	0.0	0.00%
Insurance	6.7	8.47%	1.3	30.66%	2.0	27.24%
Medicare	59.3	75.21%	2.3	56.65%	5.0	69.15%
Medicaid	7.6	9.61%	0.5	12.69%	0.3	3.61%
Other (VA and Misc.)	2.2	2.78%	-	-	-	-
<b>Total</b>	<b>78.9</b>	<b>100.00%</b>	<b>4.1</b>	<b>100.00%</b>	<b>7.2</b>	<b>100.00%</b>

Source: Section L.3(a), page 71

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 3.94% of IC dialysis services will be provided to self-pay patients, 75.21% to Medicare patients and 9.61% to Medicaid patients.

On pages 71-72, 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 bases payor mix upon treatment volumes rather than patients.
- The applicant bases future payor mix percentages on CY2020 payor mix percentages for treatment volumes.

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.

In Section L.5, page 73, 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 add no more than two dialysis stations at Carolina Dialysis-Mebane pursuant to Condition 2 of the facility need methodology for a total of no more than 27 stations upon completion of this project and Project ID# J-12080-21 (relocate 2 stations).

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-1. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- The applicant currently provides applicable health professional training programs in the area with access to the facility.
- 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 application is conforming to this criterion for all the reasons described above.

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

NC

The applicant proposes to add no more than two dialysis stations at Carolina Dialysis-Mebane pursuant to Condition 2 of the facility need methodology for a total of no more than 27 stations upon completion of this project and Project ID# J-12080-21 (relocate 2 stations).

On page 113, the 2022 SMFP defines the service area for the county need methodology 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 area: Cherokee-Clay-Graham counties and Avery-Mitchell-Yancey counties.”* Carolina Dialysis - Mebane is located in Alamance County. Thus, the service area for this application is Alamance County. Facilities may serve residents of counties not included in their service area.

As of December 31, 2021, there were seven existing or approved facilities providing dialysis and/or dialysis home training and support in Alamance County. The following table shows the existing and approved dialysis facilities in Alamance County, from Table 9A, page 121 of the 2022 SMFP:

**Alamance County Dialysis Facilities**

<b>Dialysis Facility</b>	<b>Certified Stations 12/31/2020</b>	<b>In-Center Patients 12/31/2020</b>	<b>Utilization Percent 12/31/2020</b>
Alamance County Dialysis	13	42	80.77%
BMA of Burlington	45	94	52.22%
Burlington Dialysis	16	71	110.94%
Carolina Dialysis of Mebane	24	72	75.00%
Glen Raven Dialysis	14	27	48.21%
Mebane Dialysis	10	35	87.50%
North Burlington Dialysis	18	57	79.17%
Fresenius Medical Care of Alexander County	13	49	94.23%

Source: 2022 SMFP, Table 9A

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 Alamance 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 76, the applicant states:

*“Approval of this application will allow the facility to continue serving patients who reside in the area. Consequently, 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 B, F, 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 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 Sections B and 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.”*

See also Sections B, C and L of the application and any exhibits.

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

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (19) Repealed effective January 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 existing or approved dialysis facilities owned, operated, or managed by a Fresenius Medical Care related entity located in North Carolina.

In Section O, page 81, 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 January 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.



However, the application is not conforming or conditionally conforming to all applicable Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200. The specific criteria are discussed below:

**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.

-NA- Carolina Dialysis - Mebane is an existing facility.

(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.

-NC- In Section Q, Form C, the applicant projects that Carolina Dialysis - Mebane will serve 77.3 in-center patients on 27 dialysis stations for a projected utilization of 2.86 ( $77.3 / 27 = 2.86$ ) patients per station per week for OY1. However, the applicant does not adequately demonstrate that its projected utilization is reasonable or adequately supported. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. Therefore, the application is not conforming with this Rule.

(c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.

-NC- In Section C, pages 26-30, and in Section Q, pages 84-90, the applicant provides the assumptions and methodology it used to project utilization at the facility. However, the applicant does not adequately demonstrate that the assumptions and methodology used to develop the projections required in this rule are reasonable and adequately supported. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. Therefore, the application is not conforming with this Rule.