REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conforming as Conditioned
NC = Nonconforming
NA = Not Applicable

Decision Date: November 3, 2021
Findings Date: November 3, 2021

Project Analyst: Julie M. Faenza
Co-signer: Gloria C. Hale

Project ID #: F-12131-21
Facility: INS Victory Home
FID #: 070499
County: Mecklenburg
Applicant: Independent Nephrology Services, Inc.
Project: Relocate the INS Charlotte facility to a new location, change the name to INS Victory Home and relocate no more than 5 dialysis stations from FMC Matthews for a total of no more than seven dialysis stations to be used for home training 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

Independent Nephrology Services, Inc. (hereinafter "INS" or "the applicant") proposes to relocate INS Charlotte (an existing 2-station facility dedicated exclusively to home dialysis training), to change its name to INS Victory Home (INS-VH), and to relocate five dialysis stations from FMC Matthews for a total of seven dedicated home hemodialysis (HH) training stations upon project completion.

The applicant does not propose to:

- Develop any beds or services for which there is a need determination in the 2021 State Medical Facilities Plan (SMFP)

- Offer a new institutional health service for which there are any policies in the 2021 SMFP

Therefore, Criterion (1) is not applicable to this review.

(2) Repealed effective July 1, 1987.

(3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and in particular, low income persons, racial and ethnic minorities, women, … persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to relocate INS Charlotte, an existing home dialysis training facility with two stations, change the name to INS-VH, and relocate five dialysis stations from FMC Matthews for a total of seven dedicated HH training stations upon project completion.

Patient Origin

On page 113, the 2021 SMFP defines the service area for dialysis stations as *"…the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties."* Thus, the service area for this facility consists of Mecklenburg County. Facilities may serve residents of counties not included in their service area.

The following table illustrates current and projected patient origin.

INS Charlotte Current & INS-VH Projected Patient Origin								
	Current – CY 2020 (INS Charlotte)				Projected – CY 2024 (INS-VH)			
	HH* Patients		PD** Patients		HH* Patients		PD** Patients	
	#	%	#	%	#	%	#	%
Mecklenburg	25	80.6%	47	85.5%	38	86.3%	57.1	89.1%
Cabarrus	2	6.5%	2	3.6%	2	4.6%	2	3.1%
Gaston	0	0.0%	2	3.6%	0	0.0%	2	3.1%
Greene	0	0.0%	1	1.8%	0	0.0%	0	0.0%
Stanly	2	6.5%	0	0.0%	2	4.6%	0	0.0%
Union	1	3.2%	2	3.6%	1	2.3%	2	3.1%
South Carolina	1	3.2%	1	1.8%	1	2.3%	1	1.6%
Total	**31**	**100.0%**	**55**	**100.0%**	**44**	**100.0%**	**64.1**	**100.0%**

*HH = Home hemodialysis
**PD = Home Peritoneal dialysis
Note: Table may not foot due to rounding.
Source: Section C, pages 23-24

In Section C, pages 24-29, and in the assumptions and methodology immediately following Form C in Section Q, the applicant provides the assumptions and methodology used to project patient origin. The applicant's assumptions are reasonable and adequately supported based on the following:

- The applicant clearly explains how and why growth was projected in the Mecklenburg County patient population.

- The applicant did not project growth in the number of patients at INS-HV who do not live in Mecklenburg County.

Analysis of Need

In Section C, pages 24-27 and 30-32, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below.

- There has been a national emphasis on moving patients to home dialysis because it typically results in better outcomes. Because of that, more and more patients are being referred for in-home dialysis.

- The COVID-19 pandemic has forced in-center dialysis patients to face risk of exposure multiple times per week because dialysis cannot be delayed. Having more capacity to train patients on home dialysis modalities lets ESRD patients have additional options for life-sustaining care and also helps alleviate some of the burden on the existing healthcare system due to the impacts of COVID-19.

- As part of the national emphasis on providing more home dialysis, the Centers for Medicare and Medicaid Services (CMS) has implemented a pilot program incentivizing home dialysis treatment and chose different areas of the country to implement this pilot program. Mecklenburg County is one of the areas chosen by CMS for this pilot program.

- The December 2020 ESRD Patient Origin reports showed that, for Mecklenburg County, there was a 22 percent increase in home hemodialysis (HH) patients and a 10.1 percent increase in peritoneal dialysis (PD) patients from December 2019.

- There is limited space in the current location to expand the facility. HH training involves longer and more frequent sessions for the duration of the training period than in-center dialysis. Additionally, while in-center dialysis stations can treat two or three patients each day, more than one HH patient cannot be trained on the same station in the same day.

The information is reasonable and adequately supported for the following reasons:

- There was an increase in the number and percentage of patients utilizing both types of home dialysis modalities, but especially for the HH modality, between December 2019 and December 2020.

- The CMS website discusses the pilot programs the applicant refers to.

Projected Utilization

In Section C, pages 23-24, 27-29, and on Form C in Section Q, the applicant provides historical and projected utilization, as shown in the table below.

INS Charlotte Historical & INS-VH Projected Utilization								
	Historical – CY 2020 (INS Charlotte)				Projected – CY 2024 (INS-VH)			
	HH* Patients		PD** Patients		HH* Patients		PD** Patients	
	#	%	#	%	#	%	#	%
Mecklenburg	25	80.6%	47	85.5%	38	86.3%	57.1	89.1%
Cabarrus	2	6.5%	2	3.6%	2	4.6%	2.0	3.1%
Gaston	0	0.0%	2	3.6%	0	0.0%	2.0	3.1%
Greene	0	0.0%	1	1.8%	0	0.0%	0	0.0%
Stanly	2	6.5%	0	0.0%	2	4.6%	0	0.0%
Union	1	3.2%	2	3.6%	1	2.3%	2.0	3.1%
South Carolina	1	3.2%	1	1.8%	1	2.3%	1.0	1.6%
Total	**31**	**100.0%**	**55**	**100.0%**	**44**	**100.0%**	**64.1**	**100.0%**

*HH = Home hemodialysis
**PD = Home Peritoneal dialysis
Note: Table may not foot due to rounding.

In Section C, pages 27-29, and immediately following Form C in Section Q, the applicant provides the assumptions and methodology used to project patient utilization, which are summarized below.

- The applicant begins its utilization projections with the patient census at INS Charlotte on December 31, 2020. The applicant states that on December 31, 2020, its HH patient census was comprised of 25 Mecklenburg County patients and six patients from other counties and states, and its PD patient census was comprised of 47 Mecklenburg County patients and eight patients from other counties and states.

- The Mecklenburg County Average Annual Change Rate (AACR) as published in the 2021 SMFP is 3.1 percent; however, the applicant uses a projected growth rate of 11 percent for Mecklenburg County HH patients and five percent for Mecklenburg County PD patients. The applicant states that, between December 2019 and December 2020, the number of Mecklenburg County HH patients increased by 22 percent and the number of Mecklenburg County PD patients increased by 10.1 percent.

- The applicant assumes the one PD patient from Greene County will transfer to a PD program closer to home, as Greene County is several hours away from Mecklenburg County.

- The applicant assumes no population growth for the patients residing in other counties and states who have used INS Charlotte but assumes the patients will continue to utilize HH

and PD training and support at INS Charlotte/INS-VH and adds them to the calculations when appropriate.

- The project is scheduled to begin offering services on December 31, 2022. OY1 is CY 2023. OY2 is CY 2024.

In Section C, pages 28-29, and immediately following Form C in Section Q, the applicant provides the calculations used to project the patient census for OY1 and OY2, as summarized in the tables below.

INS-VH HH Projected Utilization	
Starting point of calculations is Mecklenburg County HH patients being trained or receiving support at INS Charlotte on December 31, 2020.	25
Mecklenburg County patient population is projected forward by one year to December 31, 2021, using the applicant's growth rate of 11%.	25 X 1.11 = 27.8
Mecklenburg County patient population is projected forward by one year to December 31, 2022, using the applicant's growth rate of 11%.	27.8 X 1.11 = 30.8
The patients from other counties and states are added. This is the projected census on December 31, 2022 and the starting census for this project.	30.8 + 6 = 36.8
Mecklenburg County patient population is projected forward by one year to December 31, 2023, using the applicant's growth rate of 11%.	30.8 X 1.11 = 34.2
The patients from other counties and states are added. This is the projected census on December 31, 2023 (OY1).	34.2 + 6 = 40.2
Mecklenburg County patient population is projected forward by one year to December 31, 2024, using the applicant's growth rate of 11%.	34.2 X 1.11 = 38.0
The patients from other counties and states are added. This is the projected census on December 31, 2024 (OY2).	38.0 + 6 = 44.0

The applicant projects to train/support 40.2 patients on seven stations, which is six patients per station per year (40.2 patients / 7 stations = 5.7, which is rounded to 6), by the end of OY1 and 44 patients on seven stations, which is six patients per station per year (44.0 patients / 7 stations = 6.3, which is rounded to 6), by the end of OY2. This meets the minimum of six patients per station per year as of the end of the first operating year as required by 10A NCAC 14C .2203(d).

INS-VH PD Projected Utilization	
Starting point of calculations is Mecklenburg County PD patients being trained or receiving support at INS Charlotte on December 31, 2020.	47
Mecklenburg County patient population is projected forward by one year to December 31, 2021, using the applicant's growth rate of 5%.	47 X 1.05 = 49.4
Mecklenburg County patient population is projected forward by one year to December 31, 2022, using the applicant's growth rate of 5%.	49.4 X 1.05 = 51.8
The patients from other counties and states are added. This is the projected census on December 31, 2022 and the starting census for this project.	51.8 + 7 = 58.8
Mecklenburg County patient population is projected forward by one year to December 31, 2023, using the applicant's growth rate of 5%.	51.8 X 1.05 = 54.4
The patients from other counties and states are added. This is the projected census on December 31, 2023 (OY1).	54.4 + 7 = 61.4
Mecklenburg County patient population is projected forward by one year to December 31, 2024, using the applicant's growth rate of 5%.	54.4 X 1.05 = 57.1
The patients from other counties and states are added. This is the projected census on December 31, 2024 (OY2).	57.1 + 7 = 64.1

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

- The applicant projects future utilization based on historical utilization.
- The applicant projects growth in the Mecklenburg County HH and PD patient population by using a lower growth rate than the historical growth rate of the HH and PD patient population in Mecklenburg County over the past year.
- The applicant projects no growth for HH and PD patients residing outside of Mecklenburg County.

Access to Medically Underserved Groups

In Section C, page 35, the applicant states:

> *"…. Each of the facilities has a patient population which includes low-income persons, racial and ethnic minorities, women,* [people with disabilities]*, 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,* [disability]*, age or any other grouping/category or basis for being an underserved person."*

The applicant provides the estimated percentage of total patients for each medically underserved group during the second full fiscal year of operation following completion of the proposed project, as shown in the following table.

Medically Underserved Groups	Estimated % of Total Patients in FY 2
Low income persons	16.5%
Racial and ethnic minorities	68.1%
Women	37.4%
Persons with disabilities	0.0%
Persons 65 and older	23.1%
Medicare beneficiaries	62.6%
Medicaid recipients	2.2%

Source: Section C, page 35

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 applicant provides a statement saying it will provide service to all residents of the service area, including underserved groups, without regard for anything other than the need for dialysis services.

- The applicant states the percentages of patients for each group listed above are based on recent facility experience.

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 all the reasons described above.

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

C

The applicant proposes to relocate INS Charlotte, an existing home dialysis training facility with two stations, change the name to INS-VH, and relocate five dialysis stations from FMC Matthews for a total of seven dedicated HH training stations upon project completion.

INS Charlotte Relocation

In Section D, pages 40-42, 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. On page 40, the applicant states:

> *"INS is proposing to relocate the entire INS Charlotte home training facility to a new location in Charlotte. The home dialysis program and two dialysis stations dedicated to home hemodialysis are to be relocated. Thus all of the dialysis patients of the facility will continue to have appropriate access to dialysis care."*

According to the ESRD Data Collection Form submitted by INS Charlotte for the time period ending December 31, 2020, INS Charlotte is located at 6646 Regal Oaks Drive in Charlotte. In Section K, page 71, the applicant provides the address of the site where it proposes to relocate INS Charlotte. According to Google Maps, the two sites are slightly more than three miles apart and less than a ten-minute drive from each other.

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

- On page 42, the applicant states it does not project any significant change in the percentages of groups that are potentially underserved through the second full fiscal year following project completion.

- On page 42, the applicant states the proposed relocation will allow for more HH training capacity, which would increase access in addition to meeting the needs of the population presently utilizing the services to be relocated.

- The existing and proposed sites are within a reasonable physical and driving distance of each other.

Access to Medically Underserved Groups

In Section D, page 41, the applicant states:

> *"Fresenius Medical Care and its related facilities in North Carolina have historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender,* [disability]*, age or any other grouping/category or basis for being an underserved person. For example, Medicare (includes Medicare Advantage treatments) represented 78.82% of North Carolina dialysis treatments in Fresenius related facilities in FY 2020; Medicaid*

treatments represented an additional 6.76% of treatments in our facilities for FY 2020. Low income and medically underinsured persons will continue to have access to all services provided by Fresenius related facilities."

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

- The applicant provides a statement of its intent to continue serving medically underserved populations.

- On page 42, the applicant states it does not project any change in the percentages of groups that are potentially underserved through the second full fiscal year following project completion.

Five Stations Being Relocated from FMC Matthews

In Section D, pages 44-45, 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. The applicant states that reduction of stations will lead to higher utilization, but that FMC Matthews already offers a third evening shift and can still accommodate all the patients at the facility. The applicant further states the 2021 SMFP shows a facility need for up to 13 additional stations at FMC Matthews and commits to filing an application for the December 1, 2021 review cycle to backfill the five stations it proposes to relocate as part of this project.

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

- The applicant states it is already offering a third shift for in-center dialysis patients.

- The applicant states the facility can hold a maximum of 21 stations and proposes to file an application to backfill the stations it relocates as part of the proposed project.

On Form D in Section Q and in the assumptions and methodology immediately following Form D in Section Q, the applicant provides projected utilization, as illustrated in the following table.

FMC Matthews Historical & Projected Utilization – December 2020-2022						
	December 31, 2020		December 31, 2021		December 31, 2022	
	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients
Mecklenburg	63	74.1%	65	74.8%	67	74.6%
Union	21	24.7%	21.9	25.2%	22.8	25.4%
Other State	1	1.2%	0	0.0%	0	0.0%
Total	**85**	**100.0%**	**86.9**	**100.0%**	**89.8**	**100.0%**

In Section D, pages 43-44, and immediately following Form D in Section Q, the applicant provides the assumptions and methodology used to project patient utilization, which are summarized below.

- The applicant begins its utilization projections with the in-center patient census on December 31, 2020. The applicant states that on December 31, 2020, the in-center patient census at FMC Matthews was comprised of 63 Mecklenburg County patients, 21 Union County patients, and one patient from another state.

- The applicant assumes the one patient from another state is a transient patient and does not include that patient in future projections.

- The applicant projects the Mecklenburg County patient population will grow at a rate of 3.1 percent per year, which is the 5-year AACR for Mecklenburg County as published in the 2021 SMFP, and the Union County patient population will grow at a rate of 4.3 percent per year, which is the 5-year AACR for Union County as published in the 2021 SMFP.

In Section D, page 44, and in the assumptions and methodology immediately following Form D in Section Q, the applicant provides the calculations used to project the patient census at FMC Matthews through December 2022, as shown in the table below.

FMC Matthews Projected Utilization	
Starting point of calculations is Mecklenburg County patients dialyzing at FMC Matthews on December 31, 2020.	63
Starting point of calculations is Union County patients dialyzing at FMC Matthews on December 31, 2020.	21
Mecklenburg County patient population is projected forward by one year to December 31, 2021, using the 3.1% AACR for Mecklenburg County.	63 X 1.031 = 65
Union County patient population is projected forward by one year to December 31, 2021, using the 4.3% AACR for Union County.	21 X 1.043 = 21.9
The populations from Mecklenburg and Union counties are combined. This is the projected census on December 31, 2021.	65 + 21.9 = 86.9
Mecklenburg County patient population is projected forward by one year to December 31, 2022, using the 3.1% AACR for Mecklenburg County.	65 X 1.031 = 67
Union County patient population is projected forward by one year to December 31, 2022, using the 4.3% AACR for Union County.	21.9 X 1.043 = 22.8
The populations from Mecklenburg and Union counties are combined. This is the projected census on December 31, 2022 (starting point for proposed project).	67 + 22.8 = 89.8

The applicant projects to serve 89.8 patients on 16 stations, which is 5.6 patients per station per week (89.8 patients / 16 stations = 5.61, which is rounded to 5.6), by the end of CY 2022, when the proposed project is projected to become operational.

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

- The applicant uses the 5-year AACRs for Mecklenburg and Union counties to project growth for patients from those counties.

- The applicant adequately explains why the patient from another state is excluded from the projections.

Access to Medically Underserved Groups

In Section D, page 45, the applicant states that the relocation of five stations from FMC Matthews will not have any effect on the ability of any members of underserved groups to receive care at FMC Matthews.

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

- The applicant provides a statement of its intent to continue serving medically underserved populations.

- On page 42, the applicant states it does not project any significant change in the percentages of groups that are potentially underserved through the second full fiscal year following project completion.

- The applicant already offers a third evening shift for dialysis patients and has committed to applying to backfill the stations it proposes to relocate.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the needs of the population currently using the services to be reduced, eliminated or relocated will be adequately met following project completion for all the reasons described above.

- The applicant adequately demonstrates that the project will not adversely impact the ability of underserved groups to access these services following project completion for all the reasons described above.

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

CA

The applicant proposes to relocate INS Charlotte, an existing home dialysis training facility with two stations, change the name to INS-VH, and relocate five dialysis stations from FMC Matthews for a total of seven dedicated HH training stations upon project completion.

In Section E, page 48, the applicant states there were no other alternatives to the proposed project. The applicant states that the existing facility is already serving a large percentage of home dialysis patients and projects that growth of the home patient population will continue to increase. The applicant also states that the existing location does not allow for expansion beyond the existing two dedicated HH training stations.

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 reasonable information to explain why it believes the proposed project is the most effective alternative.

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 reasons stated above. Therefore, the application is approved subject to the following conditions:

1. **Independent Nephrology Services, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**

2. **The certificate holder shall relocate the existing INS Charlotte facility to a new location, relocate no more than five dialysis stations from FMC Matthews, and change the name of the facility to INS Victory Home.**

3. **INS Victory Home shall be certified for no more than seven dedicated home hemodialysis training stations upon project completion.**

4. **The certificate holder shall install plumbing and electrical wiring through the walls for no more than seven dedicated home hemodialysis training stations.**

5. **Upon completion of this project, Fresenius Medical Care Holdings, Inc. shall take the necessary steps to decertify five in-center stations at FMC Matthews for a total of no more than 16 in-center stations upon project completion.**

6. **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 third month. The first progress report shall be due on April 1, 2022. The second progress report shall be due on July 1, 2022 and so forth.**

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 relocate INS Charlotte, an existing home dialysis training facility with two stations, change the name to INS-VH, and relocate five dialysis stations from FMC Matthews for a total of seven dedicated HH training stations upon project completion.

Capital and Working Capital Costs

On Form F.1a in Section Q, the applicant projects the capital cost to develop the proposed project, as shown in the table below.

Construction/Renovation Contract	$1,363,183
Architect/Engineering Fees	$122,686
Non-Medical Equipment	$66,899
Furniture	$105,996
Contingency	$148,587
Total	**$1,807,351**

In Section K, pages 69-70, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant states it relied on the Fresenius Medical Care Real Estate and Construction Services team to develop the projected capital costs and that the team uses a national database to assist in projections.

- The applicant states it has relied on this team for the development of multiple projects requiring CON approval in North Carolina.

In Section F, page 51, the applicant states there are no projected working capital costs because it is an existing facility that is already operational.

Availability of Funds

In Section F, page 49, the applicant states it will fund the capital cost of the proposed project with accumulated reserves. Exhibit F-2 contains a letter from the applicant on behalf of the Senior Vice President and Treasurer of Fresenius Medical Care Holdings, Inc., the parent company of the applicant, authorizing the use of accumulated reserves for the capital needs of the project. The letter in Exhibit F-2 also states that the 2020 Consolidated Balance Sheet for Fresenius Medical Care Holdings, Inc. shows more than $446 million in cash and total assets in excess of $25 billion.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the following:

- The applicant provided a letter from an appropriate company official committing the amount of the projected capital cost to the proposed project.

- The letter from the applicant demonstrates the availability of adequate cash and assets to fund the proposed project.

Financial Feasibility

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

Projected Revenues and Operating Expenses		
INS-VH	**FY 1 (CY 2023)**	**FY 2 (CY 2024)**
Total Treatments	14,594	15,516
Total Gross Revenues (Charges)	$91,812,220	$97,613,031
Total Net Revenue	$8,027,553	$8,499,077
Average Net Revenue per Treatment	$550	$548
Total Operating Expenses (Costs)	$4,214,699	$4,518,031
Average Operating Expense per Treatment	$289	$291
Net Income/Profit	**$3,812,854**	**$3,981,046**

The assumptions used by the applicant in preparation of the pro forma financial statements are provided immediately following Form F.2 and in Forms F.3 and F.4 in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant adequately explains the assumptions used to project revenue, such as projected reimbursement rates, and operating costs, such as salaries.

- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.

- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.

- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.

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

C

The applicant proposes to relocate INS Charlotte, an existing home dialysis training facility with two stations, change the name to INS-VH, and relocate five dialysis stations from FMC Matthews for a total of seven dedicated HH training stations upon project completion.

On page 113, the 2021 SMFP defines the service area for dialysis stations as *"...the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties."* Thus, the service area for this facility consists of Mecklenburg County. Facilities may serve residents of counties not included in their service area.

There are 26 existing and approved facilities which provide in-center dialysis and/or dialysis home training and support in Mecklenburg County, 24 of which are operational. Information on all 26 of these facilities is provided in the table below.

Mecklenburg County Dialysis Facilities Certified Stations and Utilization as of December 31, 2019						
Dialysis Facility	**Owner**	**Location**	**Certified Stations**	**Utilization**	**# HH Patients**	**# PD Patients**
BMA Beatties Ford	BMA	Charlotte	39	78.85%	--	--
BMA Nations Ford	BMA	Charlotte	28	83.04%	--	--
BMA of East Charlotte*	BMA	Charlotte	26	85.58%	--	--
BMA West Charlotte*	BMA	Charlotte	29	77.59%	--	--
FKC Mallard Creek**	BMA	Charlotte	0	0.00%	--	--
FKC Regal Oaks	BMA	Charlotte	15	81.67%	--	--
FKC Southeast Charlotte	BMA	Pineville	10	32.50%	--	--
FMC Aldersgate	BMA	Charlotte	10	72.50%	--	--
FMC Charlotte	BMA	Charlotte	45	88.89%	3	7
FMC Matthews	BMA	Matthews	21	114.29%	--	--
FMC of North Charlotte	BMA	Charlotte	40	91.25%	--	--
FMC Southwest Charlotte	BMA	Charlotte	16	92.19%	6	7
INS Charlotte***	BMA	Charlotte	2	--	22	62
INS Huntersville***	BMA	Huntersville	2	--	8	24
Brookshire Dialysis	DaVita	Charlotte	10	45.00%	--	--
Carolinas Medical Center****	CMHA	Charlotte	9	--	0	11
Charlotte Dialysis	DaVita	Charlotte	34	77.94%	--	--
Charlotte East Dialysis	DaVita	Charlotte	34	76.47%	15	48
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	61.46%	0	14
DSI Glenwater Dialysis	DSI	Charlotte	42	72.02%	7	0
Huntersville Dialysis	DaVita	Huntersville	18	87.50%	--	--
Mint Hill Dialysis	DaVita	Mint Hill	22	62.50%	--	--
Mountain Island Lake Dialysis**	DaVita	Charlotte	0	0.00%	--	--
North Charlotte Dialysis Center	DaVita	Charlotte	36	70.83%	--	--
Renaissance Park Dialysis*****	DaVita	Charlotte	0	0.00%	--	--
South Charlotte Dialysis*	DaVita	Charlotte	23	80.43%	--	--
Sugar Creek Dialysis	DaVita	Charlotte	10	70.00%	--	--

Source: Table 9A, Chapter 9, 2021 SMFP; Dialysis Patient Origin Reports; Agency records

*Facility which exists and is operational, but which has been approved to relocate to a new site with additional stations.

**Facility under development or which was not operational at the time of data collection for the 2021 SMFP.

***Facility which is dedicated exclusively to providing HH and PD training and support.

****Facility with stations excluded from the inventory and need methodology calculations pursuant to Policy ESRD-3.

*****On November 13, 2020, the certificate of need to develop Renaissance Park Dialysis was relinquished.

In Section G, page 57, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Mecklenburg County. The applicant states:

> *"The applicant is not proposing to develop new dialysis stations by this proposal. The applicant proposes to relocate the INS Charlotte facility and two* [sic] *existing certified dialysis stations within Mecklenburg 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 based on the following:

- The applicant does not propose to increase the number of certified dialysis stations in Mecklenburg County.

- The applicant adequately demonstrates that the proposed relocation of the home dialysis program and dialysis stations to train HH patients is needed in addition to the existing or approved dialysis services in Mecklenburg 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 all the reasons described above.

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

C

The applicant proposes to relocate INS Charlotte, an existing home dialysis training facility with two stations, change the name to INS-VH, and relocate five dialysis stations from FMC Matthews for a total of seven dedicated HH training stations upon project completion.

On Form H in Section Q, the applicant provides current and projected staffing for the proposed services, as illustrated in the following table.

INS Charlotte Current and INS-VH Projected Staffing			
	Current	Projected	
	9/15/2021	CY 2023	CY 2024
Administrator	1.00	1.00	1.00
Home Training Nurse	6.00	7.00	8.00
Patient Care Technicians	1.50	1.50	1.50
Dietician	0.75	0.75	0.75
Social Worker	0.75	0.75	0.75
Maintenance	0.15	0.15	0.15
Admin/Business Office	1.00	1.00	1.00
Director of Operations	0.25	0.25	0.25
Chief Technician	0.10	0.10	0.10
FMC In-service	0.25	0.25	0.25
TOTAL	**11.75**	**12.75**	**13.75**

The assumptions and methodology used to project staffing are provided immediately following Form H in Section Q. Adequate operating expenses for the health manpower and management

positions proposed by the applicant are budgeted in Form F.4 in Section Q. In Section H, pages 59-60, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

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

- The applicant projects sufficient operating expenses for the staff proposed by the applicant.

- The applicant describes the required qualifications for staff, continuing education, and other training programs.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to relocate INS Charlotte, an existing home dialysis training facility with two stations, change the name to INS-VH, and relocate five dialysis stations from FMC Matthews for a total of seven dedicated HH training stations upon project completion.

Ancillary and Support Services

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

- The facility is an existing facility already providing the necessary ancillary and support services.

- The applicant describes the structure in place at both the corporate level and the facility level for providing the necessary ancillary and support services.

Coordination

In Section I, page 66, the applicant describes its existing and proposed 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 facility is an existing facility that has existing relationships with local health care and social service providers.

- The applicant provides a letter from the medical director of the facility attesting to the relationship between the medical director's physician practice and the facility.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. 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 relocate INS Charlotte, an existing home dialysis training facility with two stations, change the name to INS-VH, and relocate five dialysis stations from FMC Matthews for a total of seven dedicated HH training stations upon project completion.

In Section K, page 69, the applicant states the proposed project involves the renovation of 5,347 square feet of existing space in a medical office building. Line drawings are provided in Exhibit K-2.

On pages 71-72, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal, and power at the site. The site appears to be suitable for the proposed facility based on the applicant's representations.

On pages 69-70, the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicant relied on a specialized team to develop project costs and has relied on this specialized team in the past.

- The applicant discusses the types of features included in developing these types of facilities that promote cost savings.

On page 70, 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 based on the following:

- The applicant states the project is a necessary part of doing business to provide convenient access to care for patients.

- The applicant states the costs are absorbed by the applicant and the project will not increase costs or charges to the public.

On pages 70-71, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

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

C

In Section L, page 74, the applicant provides the historical payor mix during CY 2020 for its existing services, as shown in the tables below.

INS Charlotte Historical Payor Mix CY 2020				
	HH		PD	
Payment Source	**# Patients**	**% Patients**	**# Patients**	**% Patients**
Self-Pay	0.0	0.00%	1.7	3.06%
Insurance*	8.4	27.18%	19.2	34.95%
Medicare*	21.0	67.78%	27.5	50.06%
Medicaid*	0.2	0.56%	3.2	5.81%
Misc. (including VA)	1.4	4.48%	3.4	6.13%
Total	**31.0**	**100.00%**	**55.0**	**100.00%**

*Including any managed care plans
Note: Table may not foot due to rounding.

FMC Matthews Historical Payor Mix CY 2020 (In-Center)		
Payment Source	**# Patients**	**% Patients**
Self-Pay	3.9	4.6%
Insurance*	10.0	11.8%
Medicare*	68.4	80.5%
Medicaid*	1.1	1.3%
Misc. (including VA)	1.5	1.8%
Total	**85.0**	**100.0%**

*Including any managed care plans
Note: Table may not foot due to rounding.

In Section L, pages 75-76, the applicant provides the following comparison.

	% of Total Patients Served by INS Charlotte during CY 2020	% of Total Patients Served by FMC Matthews during CY 2020	% of the Population of Mecklenburg County
Female	37.4%	33.3%	51.9%
Male	62.6%	66.7%	48.1%
Unknown	0.0%	0.0%	0.0%
64 and Younger	76.9%	37.5%	88.5%
65 and Older	23.1%	62.5%	11.5%
American Indian	0.0%	0.0%	0.8%
Asian	1.1%	9.7%	6.3%
Black or African-American	67.0%	36.1%	33.0%
Native Hawaiian or Pacific Islander	0.0%	0.0%	0.1%
White or Caucasian	31.9%	40.3%	46.1%
Other Race	0.0%	0.0%	13.7%
Declined / Unavailable	0.0%	0.0%	0.0%

Sources: BMA Internal Data, US Census Bureau

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 76, the applicant states it has no such obligation.

In Section L, page 76, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against INS Charlotte.

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.

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

C

In Section L, page 77, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

INS-VH Projected Payor Mix CY 2024				
	HH		PD	
Payment Source	# Patients	% Patients	# Patients	% Patients
Self-Pay	0.0	0.0%	2.0	3.1%
Insurance*	11.9	27.2%	22.4	34.9%
Medicare*	29.8	67.8%	32.1	50.1%
Medicaid*	0.2	0.6%	3.7	5.8%
Misc. (including VA)	2.0	4.5%	3.9	6.1%
Total	**44.0**	**100.0%**	**64.1**	**100.0%**

*Including any managed care plans
Note: Table may not foot due to rounding.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 3.1 percent of PD services will be provided to self-pay patients; 67.8 percent of HH services and 50.1 percent of PD services to Medicare patients; and 0.6 percent of HH and 5.8 percent of PD services to Medicaid patients.

On page 77, the applicant provides the assumptions and methodology it uses to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical payor mix.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 79, the applicant adequately describes the range of means by which patients will have access to the proposed services and provides supporting documentation in Exhibit L-4.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

(14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

The applicant proposes to relocate INS Charlotte, an existing home dialysis training facility with two stations, change the name to INS-VH, and relocate five dialysis stations from FMC Matthews for a total of seven dedicated HH training stations upon project completion.

In Section M, page 80, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting

documentation in Exhibit M-2. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following:

- The applicant provides a copy of a letter sent to Central Piedmont Community College offering the facility as a training site for nursing students.

- The applicant states it often receives requests to utilize the facility for health professional training programs and discusses the options it offers when it receives such an inquiry.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

(15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.

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

C

The applicant proposes to relocate INS Charlotte, an existing home dialysis training facility with two stations, change the name to INS-VH, and relocate five dialysis stations from FMC Matthews for a total of seven dedicated HH training stations upon project completion.

On page 113, the 2021 SMFP defines the service area for dialysis stations as *"...the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties."* Thus, the service area for this facility consists of Mecklenburg County. Facilities may serve residents of counties not included in their service area.

There are 26 existing and approved facilities which provide in-center dialysis and/or dialysis home training and support in Mecklenburg County, 24 of which are operational. Information on all 26 of these facilities is provided in the table below.

Mecklenburg County Dialysis Facilities
Certified Stations and Utilization as of December 31, 2019

Dialysis Facility	Owner	Location	Certified Stations	Utilization	# HH Patients	# PD Patients
BMA Beatties Ford	BMA	Charlotte	39	78.85%	--	--
BMA Nations Ford	BMA	Charlotte	28	83.04%	--	--
BMA of East Charlotte*	BMA	Charlotte	26	85.58%	--	--
BMA West Charlotte*	BMA	Charlotte	29	77.59%	--	--
FKC Mallard Creek**	BMA	Charlotte	0	0.00%	--	--
FKC Regal Oaks	BMA	Charlotte	15	81.67%	--	--
FKC Southeast Charlotte	BMA	Pineville	10	32.50%	--	--
FMC Aldersgate	BMA	Charlotte	10	72.50%	--	--
FMC Charlotte	BMA	Charlotte	45	88.89%	3	7
FMC Matthews	BMA	Matthews	21	114.29%	--	--
FMC of North Charlotte	BMA	Charlotte	40	91.25%	--	--
FMC Southwest Charlotte	BMA	Charlotte	16	92.19%	6	7
INS Charlotte***	BMA	Charlotte	2	--	22	62
INS Huntersville***	BMA	Huntersville	2	--	8	24
Brookshire Dialysis	DaVita	Charlotte	10	45.00%	--	--
Carolinas Medical Center****	CMHA	Charlotte	9	--	0	11
Charlotte Dialysis	DaVita	Charlotte	34	77.94%	--	--
Charlotte East Dialysis	DaVita	Charlotte	34	76.47%	15	48
DSI Charlotte Latrobe Dialysis	DSI	Charlotte	24	61.46%	0	14
DSI Glenwater Dialysis	DSI	Charlotte	42	72.02%	7	0
Huntersville Dialysis	DaVita	Huntersville	18	87.50%	--	--
Mint Hill Dialysis	DaVita	Mint Hill	22	62.50%	--	--
Mountain Island Lake Dialysis**	DaVita	Charlotte	0	0.00%	--	--
North Charlotte Dialysis Center	DaVita	Charlotte	36	70.83%	--	--
Renaissance Park Dialysis*****	DaVita	Charlotte	0	0.00%	--	--
South Charlotte Dialysis*	DaVita	Charlotte	23	80.43%	--	--
Sugar Creek Dialysis	DaVita	Charlotte	10	70.00%	--	--

Source: Table 9A, Chapter 9, 2021 SMFP; Dialysis Patient Origin Reports; Agency records

*Facility which exists and is operational, but which has been approved to relocate to a new site with additional stations.

**Facility under development or which was not operational at the time of data collection for the 2021 SMFP.

***Facility which is dedicated exclusively to providing HH and PD training and support.

****Facility with stations excluded from the inventory and need methodology calculations pursuant to Policy ESRD-3.

*****On November 13, 2020, the certificate of need to develop Renaissance Park Dialysis was relinquished.

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

> *"The applicant does not expect this proposal to have any effect on the competitive climate in Mecklenburg 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 82, the applicant states:

> *"This is a proposal to relocate (and rename) the INS Charlotte dialysis facility and relocate five dialysis stations from FMC Matthews. Approval of this application will ensure continued access to care for the patients; this proposal will ensure continued convenient, affordable access to care for the growing number of home dialysis patients. This is an immediate and significantly positive impact to the patients of the area."*

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

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

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

See also Section O of the application and any exhibits.

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

> *"All Fresenius Medical Care related facilities in North Carolina have a history of providing dialysis services to the underserved populations of North Carolina. .... Each of those facilities has a patient population which includes low-income persons, racial and ethnic minorities, women,* [people with disabilities]*, 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 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,* [disability]*, age or any other grouping/category or basis for being an underserved person. Low income and medically underinsured persons will continue to have access to all services provided by Fresenius related facilities."*

See also Sections C, D, 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 adequately demonstrates that:

1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.

2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services and the applicant's record of providing quality care in the past.

3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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 all the reasons described above.

(19) Repealed effective July 1, 1987.

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

C

The applicant proposes to relocate INS Charlotte, an existing home dialysis training facility with two stations, change the name to INS-VH, and relocate five dialysis stations from FMC Matthews for a total of seven dedicated HH training stations upon project completion.

On Form O in Section Q, the applicant identifies the kidney disease treatment centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 126 existing or approved kidney disease treatment facilities located in North Carolina.

In Section O, page 87, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents resulting in an Immediate Jeopardy violation that occurred in any of these facilities. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all 126 facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

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

C

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

10 NCAC 14C .2203 PERFORMANCE STANDARDS

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

-NA- INS-VH is not a proposed new facility for in-center dialysis services. Therefore, this Rule is not applicable to this review.

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

(1) an existing dialysis facility; or
(2) a dialysis facility that is not operational as of the date the certificate of need application is submitted but has been issued a certificate of need

shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first full fiscal year of operation following certification of the additional stations.

-NA- INS-VH does not and will not offer in-center dialysis services. Therefore, this Rule is not applicable to this review.

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

-NA- INS-VH is an existing facility. Therefore, this Rule is not applicable to this review.

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

-C- In Section C, page 28, and on Form C in Section Q, the applicant projects that INS-HV will train/support 40.2 patients on seven stations, or a rate of six patients per station per year, as of the end of the first operating year following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

-C- In Section C, pages 27-29, and immediately following Form C in Section Q, the applicant provides the assumptions and methodology it used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.