

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: April 30, 2024

Findings Date: April 30, 2024

Project Analyst: Crystal Kearney

Co-Signer: Mike McKillip

Project ID #: F-12467-24

Facility: INS Freedom Dialysis

FID #: 070257

County: Mecklenburg

Applicant: Independent Nephrology Services, Inc.

Project: Relocate 4 dialysis stations from FMC Charlotte for a total of 9 dialysis stations upon project completion

### REVIEW CRITERIA

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

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

NA

Independent Nephrology Services, Inc. (hereinafter referred to as “INS Freedom Dialysis” or “the applicant”), proposes to relocate 4 dialysis stations from FMC Charlotte for a total of no more than 9 dialysis stations upon project completion.

The applicant does not propose to:

- Develop any beds or services for which there is a need determination in the 2024 State Medical Facilities Plan (SMFP).
- Acquire any medical equipment for which there is a need determination in the 2024 SMFP.

- Offer a new institutional health service for which there are any applicable policies in the 2024 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- (2) Repealed effective July 1, 1987.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 4 dialysis stations from FMC Charlotte to INS Freedom Dialysis for a total of 9 dialysis stations upon project completion. INS Freedom dialysis is a freestanding home therapy dialysis facility dedicated to providing training and support services to home hemodialysis and peritoneal dialysis patients.

**Patient Origin**

On page 113, the 2023 SMFP defines the service area for dialysis stations as “*the service area is the county in which the dialysis station is located.*” Thus, the service area for this facility consists of Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates historical and projected patient origin for in-center (IC), home hemodialysis (HH), and peritoneal dialysis (PD) patients.

INS Freedom Dialysis Historical & Projected Patient Origin												
	Historical – Full FY 2023						Projected – Full FY 2026					
	IC Patients		HH Patients		PD Patients		IC Patients		HH Patients		PD Patients	
County	#	%	#	%	#	%	#	%	#	%	#	%
Mecklenburg	0	0.0%	30.0	75.0%	45.0	84.9%	0	0.0%	31.0	75.8%	46.0	85.5%
Cabarrus	0	0.0%	2.0	5.0%	2.0	3.8%	0	0.0%	2.0	4.8%	2.0	3.6%
Gaston	0	0.0%	2.0	5.0%	2.0	3.8%	0	0.0%	2.0	4.8%	2.0	3.6%
Iredell	0	0.0%	1.0	2.5%	0	0.0%	0	0.0%	1.0	2.4%	0.0	0.0%
Lincoln	0	0.0%	2.0	5.0%	0	0.0%	0	0.0%	2.0	4.8%	.00	0.0%
Randolph	0	0.0%	0.0	0.0%	1.0	1.9%	0	0.0%	0.0	0.0%	1.0	1.8%
Richmond	0	0.0%	0.0	0.0%	1.0	1.9%	0	0.0%	0.0	0.0%	1.0	1.8%
So. Carolina	0	0.0%	3.0	7.5%	2.0	3.8%	0	0.0%	0.0	0.0%	2.0	3.6%
<b>Total</b>	<b>0</b>	<b>0.0%</b>	<b>40.0</b>	<b>100.0%</b>	<b>53.0</b>	<b>100.0%</b>	<b>0</b>	<b>0.0%</b>	<b>41.0</b>	<b>100.0%</b>	<b>54.5</b>	<b>100.0%</b>

Source: Section C, pages 23 – 24

In Section C, page 23-26, and Section Q, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable

and adequately supported because the projections are based on the applicant's historical (CY 2023) experience.

### **Analysis of Need**

In Section C, page 28, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below.

- The applicant proposes to relocate four existing dialysis stations from FMC Charlotte to INS Freedom Dialysis for a total of nine stations upon completion.
- INS Freedom Dialysis is an existing freestanding dialysis facility dedicated exclusively to home hemodialysis and peritoneal dialysis training and support services and is the predominant Fresenius Medical Care related home dialysis program operating in Charlotte and Mecklenburg County.
- The applicant proposes the relocation of these stations will increase access to home hemodialysis training and support services in the service area and will reduce the number of certified stations at the FMC Charlotte upon relocation to its new location, pursuant to CON Project ID # F-12132-21.
- The applicant states the significant home therapy growth in the Charlotte area and that there is not capacity at the FMC Charlotte replacement facility for the four stations and they would be better utilized for home therapy services at INS Freedom Dialysis facility.
- Utilizing these stations in this way will encourage greater rates of home dialysis to improve the quality of life and care for dialysis.

The information is reasonable and adequately supported based on the historical growth of the INS Freedom Dialysis patient census.

### **Project Utilization**

In Section C, pages 24-Section Q, pages 82-85, the applicant provides historical and projected utilization, which is summarized as follows:

- The applicant begins projections of the future population to be served with the facility census as of December 31, 2023. This information was reported in the ESRD Data Collection Form for the period ending December 31, 2023, and submitted to DHSR Healthcare Planning in February 2024. As of the date of this application, INS Freedom was the predominant Fresenius Medical Care related home dialysis program operating in Charlotte and Mecklenburg County. The facility is serving a total of 40 home hemodialysis patients and 53 peritoneal dialysis patients as of December 31, 2023.
- The applicant states INS Freedom dialysis has experienced significant growth in its home hemodialysis patient population, as reported to DHSR Healthcare Planning on the 2019-2023 ESRD Data Collection Forms, shown in table below.

<b>INS Freedom Dialysis</b>						
	<b>12/31/2019</b>	<b>12/31/2020</b>	<b>12/31/2021</b>	<b>12/31/2022</b>	<b>12/31/2023</b>	<b>4-Year CAGR</b>
<b>HH Patients</b>	8	11	13	23	40	49.54%

- The applicant will project growth of the Mecklenburg County patient population using a growth rate of 1.1%, as reported in the 2024 SMFP.
- The facility was serving seven home hemodialysis patients residing in Cabarrus, Gaston, Iredell and Lincoln Counties and three home hemodialysis patients residing in South Carolina, for a total of 10 out of county/state patients. Cabarrus, Gaston, Iredell, Lincoln Counties and South Carolina are all contiguous to Mecklenburg County. It is reasonable to conclude that patients residing in these areas would continue dialysis at INS Freedom Dialysis as a function of patient choice, especially given that home dialysis patients do not travel three times a week for treatment (once their training is completed) like in-center patients. The patients are assumed to continue dialysis with the facility; however, the applicant does not project any growth for this segment of the patient population. These patients will be added to projections of future patient populations at appropriate points in time.
- The facility was also serving six home peritoneal dialysis patients residing in Cabarrus, Gaston, Randolph and Richmond Counties and two home peritoneal dialysis patients residing in South Carolina, for a total of eight out of county/state patients. Cabarrus and Gaston County are contiguous to Mecklenburg. The applicant states it is reasonable that patients residing in these areas would continue dialysis at INS Freedom Dialysis as a function of patient choice, especially given that home dialysis patients do not travel three times a week for treatment (once their training is completed) like in-center patients. The patients are assumed to continue dialysis with the facility; however, the applicant does not project any growth for this segment of the patient population. These patients will be added to projections of future patient populations at appropriate points in time.
  
- The new stations are projected to be certified as of December 31,2024.
- Operating Year 1 is the period from January 1 – December 31, 2025.
- Operating Year 2 is the period from January 1 - December 31, 2026.

INS Freedom Dialysis Utilization Projections	Home Hemodialysis	Peritoneal Dialysis
Begin with the Mecklenburg County patient population as of December 31, 2023.	30.0	45.0
Project the Mecklenburg County patient population forward for one year to December 31, 2024, using a 1.1% which is consistent with Mecklenburg AACR.	$30.0 \times 1.01 = 30.3$	$45.0 \times 1.01 = 45.5$
Add the patients from other counties. This is the projected ending census for Interim Year 1.	$30.3 + 10 = 40.3$	$45.5 + 8 = 53.5$
Project the Mecklenburg County patient population forward for one year to December 31, 2025, commensurate with the Mecklenburg AACR in the 2024 SMFP.	$30.3 \times 1.01 = 30.7$	$45.5 \times 1.01 = 46.0$
Add the patients from other counties. <b>This is the projected ending census for Operating Year 1.</b>	$30.7 + 10 = 40.7$	$46.0 + 8 = 54.0$
Project the Mecklenburg County patient population forward for one year to December 31, 2025, commensurate with the Mecklenburg AACR in the 2024 SMFP	$30.7 \times 1.01 = 31.0$	$46.0 \times 1.01 = 46.5$
Add the patients from other counties <b>This is the projected ending census for Operating Year 2</b>	$31.0 + 10 = 41.0$	$46.5 + 8 = 54.5$

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

	Operating Year 1	Operating Year 2
Home Hemodialysis	40.7	41.0
Peritoneal Dialysis	54.0	54.5

Projected utilization at INS Freedom Dialysis is reasonable and adequately supported by the Mecklenburg AACR and based on the applicant’s historical utilization from 2019 to 2023.

**Access to Medically Underserved Groups**

In Section C, pages 30-31, the applicant and its parent organization, has a long history of providing dialysis services to the underserved populations of North Carolina.

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

The applicant offers the following estimated percentage of total patients for each group during the second OY following completion of the project. This estimate is based upon recent facility experience.

<b>Group</b>	<b>Estimated Percentage of Total Patients during the Second Full Fiscal Year</b>
Low income persons	51.6%
Racial and ethnic minorities	83.5%
Women	45.1%
Persons with disabilities	14.3%
Persons 65 and older	19.8%
Medicare beneficiaries	33.0%
Medicaid recipients	22.0%

Source: Section C, page 31

The applicant adequately demonstrates the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the applicant's history of providing service to all residents of the service area, including underserved groups, without regard for anything other than the need for dialysis services.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to relocate no more than 4 dialysis stations from FMC Charlotte to INS Freedom Dialysis for a total of no more than 9 dialysis stations upon project completion.

In Section D, page 37, the applicant provides the following table.

<b>FMC Charlotte</b>	<b>Dialysis Stations</b>
Total # of existing approved, and proposed dialysis stations as of the application deadline	46
Number of existing dialysis stations to be reduced, relocated or eliminated in this proposal	-4
Total # of dialysis stations upon project completion of this project and all other projects involving this facility.	42

Source: Section O, page 37

### Utilization Projections for FMC Charlotte

FMC Charlotte is currently a 48-station dialysis facility offering in-center dialysis and training and support services for both home hemodialysis and peritoneal dialysis. In Project ID# F-12136-21, FMC Charlotte was approved to relocate the entire home training program and two dialysis stations to FKC Regal Oaks. That project will be completed in 2024. Assumptions for FMC Charlotte are as follows:

1. The applicant begins projections of the future patient population to be served with the facility census as of December 31, 2023. The facility was serving 85 in-center patients, three home hemodialysis patients and 10 peritoneal dialysis patients as of December 31, 2023.
2. The applicant projects growth of the Mecklenburg County patient census using the Mecklenburg County Five Year Average Annual Change Rate (AACR) of 1.1%, as published in the 2024 SMFP.
3. The facility was serving one home hemodialysis patient residing in Gaston County and one peritoneal dialysis patient residing in Cabarrus County. Cabarrus and Gaston Counties are contiguous to Mecklenburg County. It is reasonable to assume that patients residing in Cabarrus and Gaston Counties would continue dialysis at FMC Charlotte as a function of patient choice, especially considering that home dialysis patients do not travel for dialysis three times a week (once training is completed) like in-center patients. These patients are assumed to continue dialysis with the facility; however, the applicant does not project any growth for this segment of the patient population. The patients will be added to projections of future patient populations at appropriate points in time.
4. The relocated stations are projected to be certified as of December 31, 2024. On page 38, the applicant provides the following table.

The applicant begins with the Mecklenburg County patient population as of December 31, 2023.	85
The applicant projects the Mecklenburg County patient population forward to December 31, 2024, using the Mecklenburg County Five Year Average Annual Change Rate.	$85 \times 1.01 = 85.9$
Project the Mecklenburg County patient population forward to December 31, 2025, using the County Five Year Average Annual Change Rate. <b>This is the projected ending census for Operating Year 1.</b>	$85.9 \times 1.01 = 86.9$
Project the Mecklenburg County patient population forward to December 31, 2026, using the County Five Year Average Annual Change Rate. <b>This is the projected ending census for Operating Year 2.</b>	$86.9 \times 1.001 = 87.8$

Source: Section D, page 38

As shown in the table above, the applicant projects to serve 88 patients on 42 stations at FMC Charlotte in the second operating year (CY 2026), for a utilization rate of 52.4% ( $88/42 = 2.1 / 4 = 52.4\%$ ) The utilizations projections for FMC Charlotte are reasonable and adequately supported because they are based on historical utilization.

**Access to Medically Underserved Groups**

In Section D, page 39, the applicant states the proposal relocation of four stations will not have any affect on the ability of medically underserved groups to access dialysis care.

The applicant adequately demonstrates the needs of medically underserved groups will be adequately met following completion of the project based on FMC Charlotte history of providing care to these groups.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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



- The applicant adequately demonstrates that the project will not adversely impact the ability of underserved groups to access these services following project completion for all the reasons described above.
- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

### C

The applicant proposes to relocate 4 dialysis stations from FMC Charlotte to INS Freedom Dialysis for a total of 9 dialysis stations upon project completion.

In Section E, page 42, 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 it could have chosen to not file for additional stations at INS Freedom Dialysis. However, the applicant states failure to apply for additional stations would not align with the 2019 Executive Order on Advancing Kidney Health encouraging greater rates of home dialysis to improve the quality of life and care for dialysis. Also, the applicant states failure to apply for additional stations would not address the significant growth in the home hemodialysis patient population at the INS Freedom Dialysis facility described in Section C of the application, especially considering that this facility is the predominant Fresenius Medical Care related home dialysis program operating in Charlotte and Mecklenburg County. The applicant states failure to apply for additional stations would lead to higher utilization rights potentially interrupts patient admissions to the facility and is the least effective alternative.

Apply for fewer stations - The applicant states it could have chosen to file for fewer than four stations. On page 42, the applicant states an application for fewer than four stations would have the same effect as not applying: higher utilization rates as the facility patient census increases. This is not the most effective alternative.

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

- 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

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 no more than four dialysis stations from FMC Charlotte to INS Freedom Dialysis.**
  - 3. INS Freedom Dialysis shall be certified for no more than nine dialysis stations upon completion of this project.**
  - 4. Progress Reports**
    - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
    - b. The certificate holder shall complete all sections of the Progress Report form.**
    - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
    - d. The first progress report shall be due on December 1, 2024.**
  - 5. 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 4 dialysis stations from FMC Charlotte to INS Freedom Dialysis for a total of 9 dialysis stations upon project completion.

#### **Capital and Working Capital Costs**

In Section Q, Form F.1a Capital Cost, page 90, the applicant projects the total capital cost of the project, as summarized below.

Capital Cost	Independent Nephrology Services, Inc.	Total
Non-Medical Equipment	\$3,000	\$ 3,000
Furniture	\$12,000	\$12,000
<b>Total Capital Cost</b>	<b>\$15,000</b>	<b>\$15,000</b>

In Section Q, pages 90-91, 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 information provided in Section Q, Form F.1a, pages 90-91.

In Section F page 44, The applicant states there will be no start-up costs or initial operating costs because INS Freedom Dialysis is an operational facility.

**Availability of Funds**

In Section F, page 44, the applicant states they are relying on corporate accumulated reserves of Fresenius Medical Care Holdings, Inc. to finance this project. In Exhibit F-2, the applicant provides a January 15, 2024, letter signed by the VP Corporate Tax North America for Fresenius Medical Care Holdings, Inc. confirming the proposal capital cost of the project, the availability of sufficient funds and committing the funds to project development.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the letter of commitment provided in Exhibit F-2 of the application.

**Financial Feasibility**

The applicant provided pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Form F.2, page 93, the applicant projects that revenues will exceed operating expenses in the first and second full fiscal years following completion of the project, as shown in the table below.

INS Freedom Dialysis	1 <sup>st</sup> Full FY CY2025	2 <sup>nd</sup> Full FY CY2026
Total # of Treatments	13,948	14,072
Total Gross Revenues (Charges)	\$87,745,745	\$88,526,597
Total Net Revenue	\$8,712,393	\$8,789,629
Average Net Revenue per Treatment	\$625	\$625
Total Operating Expenses (Costs)	\$5,087,262	\$5,285,714
Average Operating Expense per Treatment	\$365	\$376
<b>Net Income</b>	<b>\$3,625,131</b>	<b>\$3,503,916</b>

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q, page 93 and 94. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- Charges and expenses are based on historical facility operations projected forward.
- Payor percentages are based on historical facility operations.
- The applicant provides reasonable assumptions in determining revenue and operating expenses in preparation of Form F.2, F.3, and F.4.
- 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 4 dialysis stations from FMC Charlotte to INS Freedom Dialysis for a total of 9 dialysis stations upon project completion.

On page 113, the 2022 SMFP defines the service area for dialysis stations as “...*the service area is the county in which the dialysis station is located. Each county comprises a service area except for two multicounty service areas: Cherokee, Clay and Graham counties and Avery, Mitchell, and Yancey counties.*” Thus, the service area for this facility consists of Mecklenburg County. Facilities may serve residents of counties not included in their service area.

According to Table 9A of the 2024 SMFP, there are 25 existing or approved dialysis facilities in Mecklenburg County as shown in the following table:

**Mecklenburg County Dialysis Facilities**

Facility	Certified stations of 12/31/2022	# of IC Patients 12/31/2022	Utilization Rate 12/31/2022
BMA Beatties Ford	+	90	54.88%
BMA Nations Ford	28	90	80.36%
BMA East Charlotte	32	105	82.03%
BMA West Charlotte	29	87	75.00%
Brookshire Dialysis	11	40	90.91%
Charlotte Dialysis	33	79	59.85%
Charlotte East Dialysis	34	102	75.00%
DSI Charlotte Latrobe Dialysis	24	70	72.92%
DSI Glenwater Dialysis	42	88	52.38%
FMC Charlotte	48	88	45.83%
FMC Charlotte	0	0	0.00%
FMC Matthews	21	80	95.24%
FMC North Charlotte	40	136	85.00%
Fresenius Kidney Care Mallard Creek	12	20	41.67%
Fresenius Kidney Care Regal Oaks	17	56	82.35%
Fresenius Kidney Care Southeast Mecklenburg	17	49	72.06%
Fresenius Medical Care Aldersgate	16	51	79.69%
Fresenius Medical Care Southwest Charlotte	26	67	64.42%
Huntersville Dialysis	27	65	60.19%
INS Charlotte (to be replaced with INS Victory Home)	2	0	0.00%
INS Victory Home (replacement facility for INS Charlotte)	0	0	0.00%
Mint Hill Dialysis	21	56	66.67%
North Carolina Dialysis Center	33	94	71.21%
South Charlotte Dialysis	27	72	66.67%
Sugar Creek Dialysis	0	0	00.00%

Source: Table 9A of the 2024 SMFP

In Section G, page 50, the applicant explains why it believes its proposal would not result in the necessary duplication of existing or approved dialysis services in Mecklenburg County. The applicant states:

*“INS Freedom Dialysis is an existing facility dedicated exclusively to hemodialysis and peritoneal dialysis training and support services. The facility does not offer in-center dialysis. The applicant is not proposing to develop new dialysis stations by this proposal. The applicant proposes to relocate existing certified dialysis stations within Mecklenburg County. These stations have been previously approved and do not duplicate existing or approved services and are needed at the INS Freedom Dialysis facility to support the growing home hemodialysis patient population.”*

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based on the following:

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

### **Conclusion**

The Agency reviewed the:

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

Based on that review, the Agency concludes that the 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 4 dialysis stations from FMC Charlotte to INS Freedom Dialysis for a total of 9 dialysis stations upon project completion.

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

Position	Current Staff	1 <sup>st</sup> FFY	2 <sup>nd</sup> FFY
		CY2025	CY2026
Administrator (FMC Clinic Manager)	1.00	1.00	1.00
Registered Nurses (RNs)	3.00	5.00	6.00
Licensed Practical Nurses (LPNs)	1.00	1.00	1.00
Home Training Nurses	3.00	4.00	4.00
Technicians (PCT)	4.00	4.00	4.00
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
Other (FMC Director of Operations)	0.12	0.12	0.12
Other (FMC Chief Technician)	0.12	0.12	0.12
Other (FMC In-Service)	0.10	0.10	0.10
<b>Total</b>	<b>16.34</b>	<b>19.34</b>	<b>20.34</b>

Source: Section Q, Form H, page 102

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 51-52, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

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

- The applicant states, in Form H Assumptions, that the number of FTE positions is a function of the number of stations available and the patient census to ensure quality care and maximize cost effectiveness.
- 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 4 dialysis stations from FMC Charlotte to INS Freedom Dialysis for a total of 9 dialysis stations upon project completion.

**Ancillary and Support Services**

In Section I, page 53, the applicant identifies the necessary ancillary and support services for the proposed services. In Section I, pages 53 – 58, 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 58, 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.

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

NA

- (11) Repealed effective July 1, 1987.

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

NA

The applicant 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 ... 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, pages 66-67, the applicant provides the historical payor mix during CY2022 for its existing services, as shown in the tables below.

Primary Payor Source at Admission	INS Freedom Dialysis					
	In-center Dialysis		Home Hemodialysis		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-Pay	0	0%	0.3	1.26%	1.0	2.00%
Insurance*	0	0%	13.0	56.41%	20.1	40.10%
Medicare*	0	0%	7.2	31.13%	26.3	52.56%
Medicaid*	0	0%	1.4	5.97%	1.3	2.51%
Other	0	0%	1.2	5.22%	1.4	2.82%
<b>Total</b>	<b>0</b>	<b>0%</b>	<b>23.0</b>	<b>100.00%</b>	<b>50.0</b>	<b>100.00%</b>

Primary Payor Source at Admission	FMC Charlotte					
	In-center Dialysis		Home Hemodialysis **		Peritoneal Dialysis	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Self-Pay	6.9	7.81%	0.0	0.00%	0.8	6.88%
Insurance*	3.7	4.21%	0.5	15.72%	5.9	53.67%
Medicare*	67.3	76.45%	2.0	67.71%	3.9	35.44%
Medicaid*	8.5	9.63%	0.4	12.33%	0.4	4.01%
Other	1.7	1.89%	0.1	4.23%	0.0	0.00%
<b>Total</b>	<b>88.0</b>	<b>100.00%</b>	<b>3.0</b>	<b>100.00%</b>	<b>11.0</b>	<b>100.00%</b>

In Section L, page 67, the applicant provides the following comparison.

INS Freedom Dialysis	Last Full Operating Year	
	Percentage of Total Patients Served (All modalities combined)	Percentage of the Population of the Service Area where the Stations will be Located or Services Offered
Female	45.1%	51.6%
Male	54.9%	48.4%
Unknown		
64 and Younger	80.2%	87.8%
65 and Older	19.8%	12.2%
American Indian	0.0%	0.9%
Asian	1.1%	6.7%
Black or African American	78.0%	33.2%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	16.5%	56.4%
Other Race	4.4%	17.1%
Declined/ Unavailable		

Source: Section L, page 67

FMC Charlotte	Last Full Operating Year	
	Percentage of Total Patients Served (All modalities combined)	Percentage of the Population of the Service Area where the Stations will be Located or Services Offered
Female	52.0%	51.6%
Male	48.0%	48.4%
Unknown		
64 and Younger	64.0%	87.8%
65 and Older	36.0%	12.2%
American Indian		0.9%
Asian	4.0%	6.7%
Black or African American	86.7%	33.2%
Native Hawaiian or Pacific Islander		0.1%
White or Caucasian	4.0%	56.4%
Other Race	5.3%	17.1%
Declined/ Unavailable		

Source: Section L, page 68

### **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 68, the applicant states it has no such obligation.

The applicant further states during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against INS Freedom Dialysis.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 69, 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.

<b>INS Freedom Dialysis Projected Payor Mix CY2026</b>						
	<b>IC</b>		<b>HH</b>		<b>PD</b>	
<b>Payment Source</b>	<b># Patients</b>	<b>% Patients</b>	<b># Patients</b>	<b>% Patients</b>	<b># Patients</b>	<b>% Patients</b>
Self-Pay	0.0	0.0%	0.5	1.26%	1.1	2.00%
Insurance*	0.0	0.0%	23.1	56.41%	21.9	40.10%
Medicare*	0.0	0.0%	12.8	31.13%	28.6	52.56%
Medicaid*	0.0	0.0%	2.4	5.97%	1.4	2.51%
Misc. (including VA)	0.0	0.0%	2.1	5.22%	1.5	2.82%
<b>Total</b>	<b>0.0</b>	<b>0.0%</b>	<b>41.0</b>	<b>100.00%</b>	<b>54.5</b>	<b>100.00%</b>

Including any managed care plans  
 Source: Section L, page 69

On page 69, 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 experience of the existing dialysis facility.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 70, 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 4 dialysis stations from FMC Charlotte to INS Freedom Dialysis for a total of 9 dialysis stations upon project completion.

In Section M, page 72, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.2. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

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

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

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

and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to relocate 4 dialysis stations from FMC Charlotte to INS Freedom Dialysis for a total of 9 dialysis stations upon project completion.

On page 113, the 2024 SMFP defines the service area for the 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 also serve residents of counties not included in their service area.

According to Table 9A of the 2024 SMFP, there are 25 existing or approved dialysis facilities in Mecklenburg County as shown in the following table:

**Mecklenburg County Dialysis Facilities**

Facility	Certified stations of 12/31/2022	# of IC Patients 12/31/2022	Utilization Rate 12/31/2022
BMA Beatties Ford	+	90	54.88%
BMA Nations Ford	28	90	80.36%
BMA East Charlotte	32	105	82.03%
BMA West Charlotte	29	87	75.00%
Brookshire Dialysis	11	40	90.91%
Charlotte Dialysis	33	79	59.85%
Charlotte East Dialysis	34	102	75.00%
DSI Charlotte Latrobe Dialysis	24	70	72.92%
DSI Glenwater Dialysis	42	88	52.38%
FMC Charlotte	48	88	45.83%
FMC Charlotte	0	0	0.00%
FMC Matthews	21	80	95.24%
FMC North Charlotte	40	136	85.00%
Fresenius Kidney Care Mallard Creek	12	20	41.67%
Fresenius Kidney Care Regal Oaks	17	56	82.35%
Fresenius Kidney Care Southeast Mecklenburg	17	49	72.06%
Fresenius Medical Care Aldersgate	16	51	79.69%
Fresenius Medical Care Southwest Charlotte	26	67	64.42%
Huntersville Dialysis	27	65	60.19%
INS Charlotte (to be replaced with INS Victory Home)	2	0	0.00%
INS Victory Home (replacement facility for INS Charlotte)	0	0	0.00%
Mint Hill Dialysis	21	56	66.67%
North Carolina Dialysis Center	33	94	71.21%
South Charlotte Dialysis	27	72	66.67%
Sugar Creek Dialysis	0	0	00.00%

Source: Table 9A of the 2024 SMFP

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 73, 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. The projected patient population for the FKC Eno River facility begins with the current patient population and projects growth of that population which reflects the facility performance since opening. ... Fresenius Medical Care related facilities are compelled to operate at maximum dollar efficiency as a result of fixed reimbursement rates from Medicare and Medicaid. The majority of our patients rely upon Medicare and Medicaid to cover the expense of their treatments. In this application, the applicant projects that greater than 92.0% of the home hemodialysis and peritoneal dialysis treatments will be reimbursed at government payors (Medicare/ Medicare Advantage/ Medicaid) rates. The facility must capitalize upon every opportunity for efficiency.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 74, the applicant states:

*“The applicant is serving a significant number of dialysis patients residing in the area of the facility. 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 C, F, K and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 74, the applicant states:

*“Quality of care is always in the forefront at Fresenius Medical Care related facilities. Quality care is not negotiable. Fresenius Medical Care, parent organization for this facility, expects every facility to provide high quality care to every patient at every treatment. Our organizational mission statement captures this sentiment very well.”*

See also Section B of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 74, the applicant states:

*“As discussed in Section C, Question 6, and documented in Exhibit L.4, the facility will serve patients without regard to race, color, national origin, gender, sexual*



*orientation, age, religion, or disability and, by policy, works to make every reasonable effort to accommodate all of its patients.”*

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

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

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

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

### C

The applicant proposes to relocate 4 dialysis stations from FMC Charlotte to INS Freedom Dialysis for a total of 9 dialysis 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 125 existing or approved kidney disease treatment facilities located in North Carolina.

In Section O, page 79, 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 125 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.

### **10A NCAC 14C .2203 PERFORMANCE STANDARDS**

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

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

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

*(1) an existing dialysis facility; or*

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

*shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per station per week as of the end of the first 12 months of operation following certification of the additional stations.*

-NA- This is not an application to add in-center dialysis stations to an existing facility.

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

-NA- The applicant does not propose to establish a new dialysis facility dedicated to home hemodialysis or peritoneal dialysis. Therefore, this Rule does not apply.

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

-C- The applicant proposes to add four home hemodialysis training stations to an existing dialysis facility dedicated to home hemodialysis and peritoneal dialysis services. The facility will have a total of nine hemodialysis stations upon project completion. INS Freedom Dialysis is projected to train 56.3 home hemodialysis patients as of the end of Operating Year 1 or  $56.3 \text{ patients} / 9 \text{ stations} = 6.25 \text{ training patients per station}$ . INS Freedom Dialysis projections meet the requirement of six home hemodialysis training patients per station required by this rule.

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

-C- In Section C, pages 26-28, 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.