

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 22, 2020

Findings Date: May 22, 2020

Project Analyst: Ena Lightbourne

Team Leader: Gloria C. Hale

Project ID #: C-11837-20

Facility: INS Cleveland County

FID #: 200033

County: Cleveland

Applicant(s): Independent Nephrology Services, Inc.

Project: Develop a new dialysis facility in Shelby to provide home peritoneal dialysis training and support services

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Agency 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

The applicant, Independent Nephrology Services, Inc. proposes to develop a new kidney disease treatment center, INS Cleveland County, dedicated to providing home training and support services for peritoneal dialysis (PD) patients. The applicant does not propose to include any certified in-center stations or home hemodialysis stations as a part of the proposed project.

The applicant does not propose to add stations via either the facility need methodology, or the county need methodology published in the 2020 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations applicable to this review.

The applicant does not propose to:

- develop any beds or services for which there is a need determination in 2020 State Medical Facilities Plan (SMFP). The 2020 SMFP does not provide a need methodology for determining the need for kidney disease treatment centers dedicated to providing home PD services.
- acquire any medical equipment for which there is a need determination in the 2020 SMFP.
- offer a new institutional health service for which there are any applicable policies in the 2020 SMFP. Policy GEN-3 is not applicable to this review because the applicant does not propose to develop or offer a new institutional health service for which there is a need determination in the 2020 SMFP. Additionally, Policy GEN-4 is not applicable to this review because the proposed capital cost for the project is \$941,992, which is less than the \$2 million required for this policy to be applicable.

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, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to develop a new kidney disease treatment center, INS Cleveland County, dedicated to providing home training and support services for peritoneal dialysis (PD) patients.

On page 113, the 2020 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.*” The applicant does not propose to develop any certified in-center stations or home hemodialysis stations as a part of the proposed project.

In Section C, page 17, the applicant states that the proposed project is for a new facility which will focus on home peritoneal dialysis patients, therefore, there is no historical patient origin information to report. The following table illustrates projected patient origin.

Projected Patient Origin INS Cleveland County Operating Year 2, CY 2022		
County	# of PD Patients	% of Total
Cleveland	22.68	100.00%
Total	22.68	100.00%

Source: Section C, page 17

The table above indicates that the second operating year is calendar year 2022. However, throughout the application, including the applicant's methodology for projected utilization, the second operating year is calendar year 2023. The Project Analyst assumes the applicant made a typographical error in the above table.

In Section C, pages 18-26, the applicant provides the assumptions and methodology used to project its patient origin for peritoneal dialysis services. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 26-27, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On pages 26-27, the applicant states:

- Failure to receive dialysis care will lead to the patient's demise.
- The proposed facility will provide routine follow-up care, ensure patient dialysis supplies are delivered and will be available for consultation with the patient as needed.
- Dialysis treatment that is scheduled at times that are not convenient for the patient can lead to higher missed treatment rates. Home dialysis affords the patient maximum flexibility with scheduling treatment times which are convenient, and in the patient's home.
- The proposed facility will focus exclusively on home peritoneal dialysis which will allow enhanced patient training opportunities while allowing the facility to enable more patients to dialyze at home.

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

- Home dialysis provide patients with flexibility, convenience, and avoidance of possible missed treatments.
- The proposed facility will enable more patients to dialyze at home in Cleveland County.

Projected Utilization

In Section Q, page 71, the applicant provides projected utilization, as illustrated in the following table.

INS Cleveland County – Projected Patient Utilization				
	Operating Year 1 CY 2022		Operating Year 2 CY 2023	
County	# of PD Patients	% of Total	# of PD Patients	% of Total
Cleveland	22.36	100.00%	22.68	100.00%

In Section C, pages 18-26 and Section Q, pages 72-77, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

Assumptions

- The applicant is proposing a new kidney disease treatment center to be utilized exclusively for peritoneal patients. The applicant does not have a dialysis facility in Cleveland County, however, the applicant states that Fresenius Medical Care, co-applicant and majority interest in Independent Nephrology Services, Inc., is currently serving patients who reside in Cleveland County. In addition, Metrolina Nephrology and Associates, the minority interest in Independent Nephrology Services, Inc., is serving patients who reside in Cleveland County and have some advanced stage of chronic kidney disease. Metrolina Nephrology and Associates also admits patients to Fresenius related facilities in Gaston, Mecklenburg, Lincoln, Union, Stanly and Anson counties.
- The applicant assumes that patients residing in Cleveland County will prefer to receive dialysis care within their home county. This would include home dialysis patients.

The ESRD patient population as of December 31, 2018 in Cleveland County was 242 patients, as published in the 2020 SMFP. Home dialysis made up 7.9% of the patients. The applicant assumes that the Cleveland County ESRD patient population will continue to grow at a rate 1.6%, which is the Cleveland County Five-Year Average Annual Change Rate (AACR), as published in the 2020 SMFP.

- The applicant projects that more patients will be referred to home dialysis based on the Executive Order on Advancing American Kidney Health. One of the goals of the Executive Order is to increase the rate of home dialysis nationwide.¹ The applicant states that this has already been experienced at Fresenius facilities.
- The applicant projects that more patients in North Carolina will choose home dialysis. To illustrate its projection, the applicant uses data from the 2020 SMFP. In Table 9A: Dialysis Data by County of Patient Origin, as of December 31, 2018, out of the 18,732 dialysis patients, 481 were home hemodialysis patients and 1,899 were home peritoneal dialysis patients. The applicant states that this indicates the four out of five home dialysis patients are choosing peritoneal dialysis. In addition, Table 9A reports that as of December 31, 2018, 63.16% of home patients in Cleveland County were peritoneal

¹ <https://www.whitehouse.gov/presidential-actions/executive-order-advancing-american-kidney-health/>

patients. The applicant states that peritoneal dialysis is the predominant modality for home dialysis patients residing in Cleveland County.

- The applicant assumes that the ESRD patient population can achieve a home penetration of at least 25%. Using data from Table 9C: ESRD Dialysis Station Need Determinations by Planning Area, of the 2020 SMFP, the applicant reviewed counties that had a 20% or higher rate of home patients and compared them to the overall ESRD population for that county. The applicant states that the 20% or higher rate of home patients in some counties may be due to a smaller ESRD census or the lack of a dialysis facility in the county. The applicant pulls the two counties with the highest percentage of home patients and ESRD census and compared them to Cleveland County data, as shown in the table below.

County	% of Home Patients	ESRD Census
Buncombe	23.90%	272
Cleveland	7.90%	242
Craven	21.20%	193

Source: Section Q, page 74

The applicant states that Cleveland County’s ESRD census is midpoint between Buncombe and Craven County, however, the percentage of home patients is significantly smaller. The applicant states that this suggests that more patients can dialyze at home. The applicant assumes that they will choose home dialysis due scheduling flexibility. This will reduce the demand on dialysis facilities and in-center utilization.

- The applicant assumes that Metrolina Nephrology and Associates will refer more patients to the proposed facility based on their support of the project and letters of support provided in Exhibit H-4.
- The applicant projects a 25% rate of home patients in Cleveland County, stating that INS facilities in Mecklenburg County recently experienced significant growth in home PD patients. However, the applicant refers to the certification of Edgecombe Home Dialysis to demonstrate the increase in home dialysis patients in Edgecombe County. According to data from the Semiannual Dialysis Reports (SDR), the number of home patients more than doubled between July 2016 and July 2019 reporting, as demonstrated in the table below.

Edgecombe County ESRD Census				
SDR	July 2016	July 2017	July 2018	July 2019
Date of Data	12/31/2015	12/31/2016	12/31/2017	12/31/2018
ESRD	214	230	224	247
Home	16	17	27	36
Home %	0.0748	0.0739	0.1205	0.1457

Source: Section Q, page 75

The applicant states that the opening of Edgecombe Home Dialysis is the reason for the increase in home dialysis patients in Edgecombe County and projects similar results with the proposed INS Cleveland County.

- The applicant assumes that the PD and home hemodialysis patient population ratio in Cleveland County will remain constant since the applicant is not proposing to offer home hemodialysis services and support in Cleveland County.
- The applicant assumes a 25% increase in home patient penetration in Cleveland County by December 31, 2021, occurring incrementally over three years from 2018 to the certification date of the proposed facility.
- The applicant assumes 50% of future PD patients will choose INS Cleveland County because they will want to receive care at a facility in their home county and based on physician support and their intention to refer patients.
- The applicant states that the project is expected to be completed by December 31, 2021.

Operating Year 1: January 1 through December 31, 2022

Operating Year 2: January 1 through December 31, 2023

Projected Utilization

In Section C, pages 23-26 and Section Q, pages 77-81, the applicant provides the calculations used to arrive at the projected PD patient census for OY1 and OY2, as summarized below.

Methodology

The applicant begins with ESRD patient population of Cleveland County as of December 31, 2018:

Total ESRD Population	
In-Center	223
Home Hemodialysis	7
Peritoneal Dialysis	12
Total	242

% of Total ESRD Population	
Home Patients	7.85%
Peritoneal Dialysis Patients	4.96%

Home patients represents 7.85% of the total population. PD represents 4.96% of the total population.

The applicant states that of the 19 home patients, all seven home hemodialysis patients were served in Fresenius related facilities in Gaston County. Five of the 12 PD patients were served in a Fresenius related facility in Gaston County. Fresenius-related facilities will report at least eight Cleveland County residents were peritoneal dialysis patients as of December 31, 2019. The applicant states that this is based on ESRD Data Collection Forms submitted to the Agency and assumes these eight patients will receive their home care and follow-up through INS Cleveland County and transfer upon certification of the facility.

Project Cleveland County patients forward one year to December 31, 2019, using the Cleveland County Five Year AACR of 1.6%.	$242 \times 1.016 = 245.9$
Project the number of home patients of Cleveland County as of December 31, 2019 by increasing the percent of home patients from 7.85% to 13.57% (5.72 incremental change as home % increases to 25% by December 31, 2021). Subtract the 19 home patients (as of December 31, 2018) from the projected 33.36.	$245.9 \times .1357 = 33.36$ $33.36 - 19 = 14.36$
Project Cleveland County patients forward one year to December 31, 2020, using the Cleveland County Five Year AACR of 1.6%.	$245.9 \times 1.016 = 249.8$
Project the number of home patients of Cleveland County as of December 31, 2020 by increasing the percent of home patients from 13.57% to 19.28% (5.71 incremental change as home % increases to 25% by December 31, 2021). Subtract the 19 home patients (as of December 31, 2018) from the projected 48.2.	$249.8 \times .1928 = 48.2$ $48.2 - 19 = 29.17$
Project Cleveland County patients forward one year to December 31, 2021, using the Cleveland County Five Year AACR of 1.6%.	$249.8 \times 1.016 = 253.8$
Project the number of home patients of Cleveland County as of December 31, 2021 by increasing the percent of home patients from 19.28% to 25.00% (5.72 incremental change as home % increases to 25% by December 31, 2021). Subtract the 19 home patients (as of December 31, 2018) from the projected 63.5.	$253.8 \times .25 = 63.5$ $63.5 - 19 = 44.45$
Project the number of new PD patients by multiplying the % of PD patients by number of new home patients.	$63.16\% \times 44.45 = 28.07$
The applicant assumes 50% (14.04) of new PD home patients will transfer to INS Cleveland County by December 31, 2021. Add the new patients to the eight patients served by Fresenius-related facilities as of December 31, 2021. This is the projected starting census for this project.	$8 + 14.04 = 22.04$
Project Cleveland County patients forward one year to December 31, 2022, using the Cleveland County Five Year AACR of 1.6%.	$253.8 \times 1.016 = 257.9$
Project the number of home patients of Cleveland County as of December 31, 2022 by maintaining the percent of home patients at 25.00%. Subtract the 19 home patients (as of December 31, 2018) from the projected 64.5.	$257.9 \times .25 = 64.5$ $64.5 - 19 = 45.47$
Project the number of new PD patients by multiplying the % of PD patients by number of new home patients.	$63.16\% \times 45.47 = 28.72$
The applicant assumes 50% (14.36) of new PD home patients will transfer to INS Cleveland County by December 31, 2021. Add the new patients to the eight patients served by Fresenius-related facilities as of December 31, 2022. This is the ending PD patient census for INS Cleveland County for Operating Year 1.	$8 + 14.36 = 22.36$
Project Cleveland County patients forward one year to December 31, 2023, using the Cleveland County Five Year AACR of 1.6%.	$257.9 \times 1.016 = 262.0$
Project the number of home patients of Cleveland County as of December 31, 2023 by maintaining the percent of home patients at 25.00%. Subtract the 19 home patients (as of December 31, 2018) from the projected 65.5.	$262.0 \times .25 = 65.5$ $65.5 - 19 = 46.50$
Project the number of new PD patients by multiplying the % of PD patients by number of new home patients.	$63.16\% \times 46.50 = 29.37$
The applicant assumes 50% (14.68) of new PD home patients will transfer to INS Cleveland County by December 31, 2021. Add the new patients to the eight patients served by Fresenius-related facilities as of December 31, 2023. This is the ending PD patient census for INS Cleveland County for Operating Year 2.	$8 + 14.68 = 22.68$

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

- The applicant projects future utilization based on historical utilization of all ESRD patients (IC, PD and HH) who are residents of Cleveland County and uses reasonable growth projections.
- Future growth of all Cleveland County ESRD patients is based on the Five-Year AACR for Cleveland County.
- The applicant projects that the home patient penetration of Cleveland County will increase to 25% incrementally by December 31, 2021 based on the recent growth of PD patients experienced at INS facilities in Mecklenburg.
- The applicant assumes that more patients can dialyze at INS Cleveland County since their home penetration was 7.9% in comparison to Buncombe and Craven counties' home penetration of over 20% as of December 31, 2018, who have patient populations that are similar in size.
- The applicant cites the Executive Order on Advancing American Kidney Health issued on July 10, 2019 by President Trump which encourages more home-based dialysis.
- The applicant references the patient census of Edgecombe Home Dialysis increasing from five PD patients as of December 31, 2017 to 35 PD patients as of December 31, 2019 as documented by ESRD Data Collection Forms submitted to the Agency.
- The applicant's representation that Fresenius Medical Care has experienced a significant shift in referral numbers for home dialysis since the second half of 2019.
- The applicant provides physician letters of support from Metrolina Nephrology Associates in Exhibit H-4.

Access

In Section C, pages 28-29, the applicant states:

“Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.

...

It is corporate policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.

...

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

In Section L, page 53, 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 Cleveland County Projected Payor Mix Operating Year 2, CY 2023		
Payor Category	# PD of Patients	Percent of Total
Self-Pay	2.01	8.85%
Medicare*	7.24	31.92%
Medicaid*	0.43	1.89%
Insurance*	9.72	42.87%
Other: Misc. Incl. VA	3.28	14.46%
Total	22.68	100.00%

* Including managed care plans

The projected payor mix is reasonable and adequately supported based on the following:

- The payor mix is based on Fresenius Medical Care experience at INS Huntersville in Mecklenburg County.
- The payor mix is solely based on peritoneal dialysis services.

Conclusion

The Agency reviewed the:

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

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

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

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

NA

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

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

C

The applicant proposes to develop a new kidney disease treatment center, INS Cleveland County, dedicated to providing home training and support services for peritoneal dialysis (PD) patients.

In Section E, page 34, applicant states that the only alternative was to apply for a new kidney disease treatment center. The applicant states that the purpose in developing the facility is to better serve the ESRD population in Cleveland County choosing home peritoneal dialysis. The applicant goes on to say that emphasis on expanding home dialysis therapies will result in more patients choosing home dialysis.

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 credible information to explain why it believes the proposed project is the most effective alternative.
- The proposed project will allow more patients to choose home dialysis in Cleveland County.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

1. **Independent Nephrology Services, Inc. shall materially comply with all representations made in the certificate of need application.**
 2. **Independent Nephrology Services, Inc. shall establish a freestanding home dialysis training and support program to provide only peritoneal dialysis training and support services.**
 3. **Independent Nephrology Services, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to develop a new kidney disease treatment center, INS Cleveland County, dedicated to providing home training and support services for peritoneal dialysis (PD) patients.

Capital and Working Capital Costs

In Section Q, page 83, the applicant projects the total capital cost of the project, as shown in the table below.

INS Cleveland County Capital Costs	
Construction/Renovation Contract(s)	\$733,745
Architect/Engineering Fees	\$66,037
Furniture	\$102,221
Other: Contingency	\$39,989
Total	\$941,992

In Section Q, page 83, the applicant provides the assumptions used to project the capital cost.

In Section F, page 36, the applicant projects that start-up costs will be \$209,480 and initial operating expenses will be \$656,100 for a total working capital of \$865,580. On pages 37-38, the applicant provides the assumptions and methodology used to project the working capital needs of the project.

Availability of Funds

In Section F, page 35, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing

Type	Independent Nephrology Services, Inc	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$941,992	\$941,992
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$941,992	\$941,992

* OE = Owner's Equity

In Section F, page 38, the applicant states that the working capital needs of the project will be funded, as shown in the table below.

Sources of Financing for Working Capital		Amount
(a)	Loans	\$0
(b)	Cash or Cash Equivalents, Accumulated Reserves or Owner's Equity	\$865,580
(c)	Lines of credit	\$0
(d)	Bonds	\$0
(e)	Total *	\$865,580

Exhibit F-2 contains a letter dated January 15, 2020, from the Senior Vice President and Treasurer for Fresenius Medical Care Holdings, Inc., authorizing and committing cash reserves for the capital costs and working capital costs of the project. The letter states that accounting for 2019 has not been completed, however, 2018 consolidated balance sheets reflect more than \$1.8 billion in cash, and total assets exceeding \$20 billion.

Financial Feasibility

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

INS Cleveland County	Operating Year 1 CY 2022	Operating Year 2 CY 2023
Total Treatments	3,285.2	3,333.0
Total Gross Revenues (Charges)	\$20,667,255	\$20,968,137
Total Net Revenue	\$2,275,124	\$2,308,246
Average Net Revenue per Treatment	\$692.54	\$692.54
Total Operating Expenses (Costs)	\$1,312,200	\$1,336,616
Average Operating Expense per Treatment	\$399.42	\$401.02
Net Income	\$962,924	\$971,630

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application

for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) 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 based on the following:

- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions.
 - The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal.
 - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to develop a new kidney disease treatment center, INS Cleveland County, dedicated to providing home training and support services for peritoneal dialysis (PD) patients.

On page 113, the 2020 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.”* The applicant does not propose to develop any certified in-center stations or home hemodialysis stations as a part of the proposed project.

According to Table 9B, page 153 of the 2020 SMFP, there are four existing dialysis facilities in Cleveland County, all of which are owned or operated by DCI. According to the most recent ESRD Data Collection Forms submitted to the Agency, home PD services are currently available at the Dialysis Clinic - Shelby facility. The existing and approved Cleveland County dialysis facilities are shown below:

Cleveland County Dialysis Facilities as of December 31, 2018						
Facility	Certified Stations as of 12/31/2018	# of In-center Patients as of 12/31/2018	Utilization by Percent as of 12/31/2018	Patients Per Station Per Week	# HH Patients	# PD Patients
DCI South	14	52	92.86%	3.7142	0	0
Dialysis Clinic - Kings Mountain	15	38	63.33%	2.5333	0	0
Dialysis Clinic - Shelby	33	92	69.70%	2.7879	0	8
Dialysis Clinic, Inc.	15	26	43.33%	1.7333	0	0
Total	77	208			0	8

Source: Table 9B of the 2020 SMFP, ESRD Data Collection Forms

In Section G, page 41, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved PD services in Cleveland County. The applicant states:

“The project does not involve dialysis stations. The project does involve development of a new kidney disease treatment center. The new center will serve exclusively home peritoneal dialysis patients.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area because the project involves the development of a new facility that will exclusively serve home peritoneal dialysis patients.

Conclusion

The Agency reviewed the:

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

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

- (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

In Section Q, page 92, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Projected FTE Staff
	Operating Year 2 CY 2023
Administrator (FMC Clinic Manager)	1.00
Home Training Nurse	3.00
Technicians (PCT)	1.00
Dietician	0.50
Social Worker	0.50
Maintenance	0.10
Administrative/Business Office	0.75
Other: FMC Director of Operations	0.15
Other: In-Service	0.10
Other: Chief Tech	0.05
TOTAL	7.15

The assumptions and methodology used to project staffing are provided in Section Q, page 93. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.4, which is found in Section Q. In Section H.2 and H.3 on page 42, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs. In Section H, page 43, the applicant identifies the proposed medical director. In Exhibit H-4, the applicant provides a letter from the proposed medical director indicating an interest in serving as medical director for the proposed services.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

In Section I, page 44, the applicant states that the following ancillary and support services are necessary for the proposed services:

INS Cleveland County– Ancillary and Support Services	
Services	Provider
Self-Care Training	Provided on site by the applicant
Home Training (1) Home Hemodialysis (2) Home Peritoneal Dialysis (3) Accessible follow-up program	Referral to BMA Kings Mountain (Gaston County) Provided on site by the applicant Provided on site by the applicant
Isolation for hepatitis B positive patients Nutritional Counseling Social Work Services Laboratory Services	Provided on site by the applicant
Back-up In-Center Dialysis	Referral to BMA Kings Mountain (Gaston County)
Vascular Surgery	Referral to Metroview Vascular and Surgical, Gastonia; Vein Specialists of the Carolinas, Gastonia; Dr. Paul Kochupua, Gastonia.
Pediatric Nephrology	Referral to Atrium Health - CMC
Acute dialysis in an acute care setting	Referral to Atrium Health - CMC
Transplantation Services	Provided by facility staff until ambulance arrival
Emergency Care	Referral to Atrium Health - Cleveland
Blood bank services	Referral to Atrium Health - Cleveland
X-Ray, Diagnostic and Evaluation Services	Referral to Atrium Health - Cleveland
Psychological Counseling	Referral to Cleveland-Monarch
Vocational Rehabilitation Counseling and Services	Referral to Cleveland Vocational Industries Inc. or, NC DHHS Vocational Rehabilitation Western Regional Office
Transportation	TACC – Transportation Administration of Cleveland County

On page 44, the applicant adequately explains how each ancillary and support service will be made available and provides supporting documentation in Exhibits I-1.1, I-1.2, I-1.3 and I-1.4.

In Section I, page 45, the applicant describes its efforts to develop relationships with other local health care and social service providers and provides supporting documentation in Exhibits I-1.1, I-1.2, I-1.3 and I-1.4.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

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

NA

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

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction

project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C

In Section K, page 47, the applicant states that the project involves up fitting 3,400 square feet of leased space. Line drawings are provided in Exhibit K-2.

On pages 47-48, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal.

On page 48, 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.

On pages 48-49, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

On pages 49-50, 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 and provides supporting documentation in Exhibit K-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.

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

NA

Neither the applicant nor any related entities owns, operates or manages an existing health service facility located in the service area. Therefore, Criterion (13a) is not applicable to this review.

- (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 handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

NA

Neither the applicant nor any related entities owns, operates or manages an existing health service facility located in the service area. Therefore, Criterion (13b) is not applicable to this review.

- (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 53, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

INS Cleveland County Projected Payor Mix Operating Year 2, CY 2023		
Payor Category	# PD of Patients	Percent of Total
Self-Pay	2.01	8.85%
Medicare*	7.24	31.92%
Medicaid*	0.43	1.89%
Insurance*	9.72	42.87%
Other: Misc. Incl. VA	3.28	14.46%
Total	22.68	100.00%

*Including managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 8.85% of total services will be provided to self-pay patients, 31.92% to Medicare patients and 1.89% to Medicaid patients.

On pages 52-53, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- The payor mix is based on Fresenius Medical Care experience at INS Huntersville in Mecklenburg County.
- The payor mix is solely based on peritoneal dialysis services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 54, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section M, page 55, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M-2.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

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

C

The applicant proposes to develop a new kidney disease treatment center, INS Cleveland County, dedicated to providing home training and support services for peritoneal dialysis (PD) patients.

On page 113, the 2020 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.*” The applicant does not propose to develop any certified in-center stations or home hemodialysis stations as a part of the proposed project.

According to Table 9B, page 153 of the 2020 SMFP, there are four existing dialysis facilities in Cleveland County, all of which are owned or operated by DCI. According to the most recent ESRD Data Collection Forms submitted to the Agency, home PD services are currently available at the Dialysis Clinic - Shelby facility. The existing and approved Cleveland County dialysis facilities are shown below:

Cleveland County Dialysis Facilities as of December 31, 2018						
Facility	Certified Stations as of 12/31/2018	# of In-center Patients as of 12/31/2018	Utilization by Percent as of 12/31/2018	Patients Per Station Per Week	# HH Patients	# PD Patients
DCI South	14	52	92.86%	3.7142	0	0
Dialysis Clinic - Kings Mountain	15	38	63.33%	2.5333	0	0
Dialysis Clinic - Shelby	33	92	69.70%	2.7879	0	8
Dialysis Clinic, Inc.	15	26	43.33%	1.7333	0	0
Total	77	208			0	8

Source: Table 9B of the 2020 SMFP, ESRD Data Collection Forms

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 56, the applicant states:

“The applicant does not project to serve dialysis patients currently being served by another provider. The applicant has not forecast any patients to change dialysis providers.

...

There is a nation-wide interest and support for expansion of home dialysis services.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 56, the applicant states:

“Fresenius 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 greater than 33% of the treatments will be reimbursed at government payors (Medicare/Medicaid) rates.”

Regarding the impact of the proposal on quality, in Section N, page 57, the applicant states:

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 57, the applicant states:

“It is corporate policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved.”

Considering all the information in the application, 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 (see Sections C, F, N and Q of the application and any exhibits)
- Quality (see Sections C, N and O of the application and any exhibits)
- Access to medically underserved groups (see Sections C, L and N of the application and any exhibits)

Conclusion

The Agency reviewed the:

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

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

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

C

In Section Q, pages 65-70, 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 of this type of facility located in North Carolina.

In Section O, page 62, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents of immediate jeopardy have not occurred in any of these facilities. After reviewing and considering information provided by the applicant and considering the quality of care provided at all 125 facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

- (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.

NA

The applicant proposes to develop a new kidney disease treatment center dedicated to providing home training and support services for PD patients. The applicant does not propose to include any certified in-center stations or home hemodialysis stations as a part of the proposed project. The Criteria and Standards for End Stage Renal Disease Services, promulgated in 10A NCAC 14C .2200, are not applicable to this review due to a declaratory ruling issued by the Agency on October 10, 2018, which exempts the Criteria and Standards from applying to proposals to develop or expand facilities exclusively serving HH and PD patients.