ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

Decision Date:	May 15, 2020
Findings Date:	May 15, 2020
Project Analyst:	Julie M. Faenza
Team Leader:	Gloria C. Hale
Project ID #:	F-11842-20
Facility:	INS Huntersville
FID #:	070257
County:	Mecklenburg
Applicant:	Independent Nephrology Services, Inc.
Project:	Relocate INS Huntersville to a new location and relocate no more than 3 dialysis stations from BMA Beatties Ford for home hemodialysis training and support services. Upon project completion, the facility will have a total of 5 dialysis stations and will be renamed INS Freedom Dialysis

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.

C

Independent Nephrology Services, Inc. (hereinafter referred to as "INS" or "the applicant") proposes to relocate INS Huntersville (INS-H), its existing facility with two dialysis stations dedicated to home hemodialysis (HH) and peritoneal dialysis (PD) training and support, to a new location in Mecklenburg County. The applicant also proposes to relocate three existing dialysis stations from BMA Beatties Ford (Beatties Ford) to its new location. Upon completion of the proposed project, the standalone kidney disease treatment center offering training and support exclusively for HH and PD patients will have five dialysis stations and will be renamed INS Freedom Dialysis (INS-FD).

Need Determination

Chapter 9 of the 2020 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. Table 9D on page 170 of the 2020 SMFP does not show a need for additional stations in Mecklenburg County based on the county need methodology. The facility need methodology in Chapter 9 of the 2020 SMFP is calculated based on the number of in-center patients; because INS-H does not have in-center patients, it cannot generate a facility need. This application is a proposal to relocate an existing dialysis facility, along with relocating three existing dialysis stations from one facility to another, and neither the county need methodology nor the facility need methodology apply. Therefore, there are no need determinations applicable to this review.

Policies

There is one policy in the 2020 SMFP which is applicable to this review. *Policy ESRD-2: Relocation of Dialysis Stations*, on page 20 of the 2020 SMFP, states:

> *"Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties. Certificate of need applicants proposing to relocate dialysis stations to a contiguous county shall:*
>
> 1. *Demonstrate that the facility losing dialysis stations or moving to a contiguous county is currently serving residents of that contiguous county; and*
>
> 2. *Demonstrate that the proposal shall not result in a deficit, or increase an existing deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina State Medical Facilities Plan, and*
>
> 3. *Demonstrate that the proposal shall not result in a surplus, or increase an existing surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina State Medical Facilities Plan."*

Both Beatties Ford and INS-H are in Mecklenburg County. Therefore, the application is consistent with Policy ESRD-2.

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 because the application is consistent with Policy ESRD-2.

(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

INS proposes to relocate INS-H to a new location in Mecklenburg County. The applicant also proposes to relocate three existing dialysis stations from Beatties Ford to its new location. Upon completion of the proposed project, the standalone kidney disease treatment center offering training and support exclusively for HH and PD patients will have five dialysis stations and will be renamed INS-FD.

In Section A, page 5, the applicant states that INS is a joint venture between Fresenius Medical Care Holdings, Inc. (FMC) (the majority owner) and Metrolina Nephrology (the minority owner).

INS-H was first certified in 2007 as a freestanding kidney disease treatment center to provide exclusively PD patient training and support. Because PD does not involve the use of dialysis stations, there were no dialysis stations at INS-H when it opened. INS-H had attempted to create a freestanding facility dedicated to training and support exclusively for home dialysis modalities prior to October 2018 but was unsuccessful due to the performance standard promulgated in 10A NCAC 14C .2203 at that time, which required dialysis stations and kidney disease treatment facilities to reasonably project a utilization rate of at least 3.2 patients per station per week prior to developing new stations or relocating stations. 10A NCAC 14C .2203, at that time, did not distinguish between in-center stations and stations used exclusively for HH patient training and support. In the application for Project I.D. #F-11638-18, creating INS-H, the applicant described the training schedule for a typical HH patient, which averages four training sessions per week, with each session lasting approximately six hours, and thus a dialysis station being used at a facility exclusively providing home training and support could not meet the performance standard as it existed at the time.

On August 8, 2018, FMC requested a declaratory ruling from the Agency stating that the requirements of 10A NCAC 14C .2203 will not apply to facilities exclusively serving PD and HH patients. On October 10, 2018, the Agency issued the declaratory ruling FMC had asked for, noting in the declaratory ruling that 10A NCAC 14C .2203 was being designated as necessary with substantive public interest so that when it was re-promulgated, the Rule could be changed to make it clear that 10A NCAC 14C .2203 applies only to in-center dialysis stations and a performance standard for HH stations could be added.

Temporary Rule 10A NCAC 14C .2203 went into effect on February 1, 2020, and states that any applicable performance standards apply to in-center dialysis patients.

Patient Origin

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."* Thus, the service area for this facility consists of Mecklenburg County. Facilities may serve residents of counties not included in their service area.

The following table illustrates current and projected patient origin.

INS-H – Current and INS-FD – Projected Patient Origin								
County	Current (12/31/2019)				Projected (OY 2 – CY 2023)			
	HH Patients		PD Patients		HH Patients		PD Patients	
	# Patients	% Total	# Patients	% Total	# Patients	% Total	# Patients	% Total
Mecklenburg	5	62.50%	20	83.33%	8.75	74.46%	23.58	85.50%
Cabarrus	2	25.00%	2	8.33%	2.00	17.03%	2.00	7.25%
Iredell	1	12.50%	0	0.00%	1.00	8.51%	0.00	0.00%
Lincoln	0	0.00%	2	8.33%	0.00	0.00%	2.00	7.25%
Total	**8**	**100.00%**	**24**	**100.00%**	**11.75**	**100.00%**	**27.58**	**100.00%**

Table may not foot due to rounding.
Source: Section C, page 17

In Section C, pages 18-20, the applicant provides the assumptions and methodology it used to project patient origin. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 18-25, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant explains the typical three day per week schedule for in-center patients to receive dialysis and states that the failure to receive dialysis services will lead to patient death. On page 21, the applicant states:

> *"Home dialysis patients – PD and home hemodialysis – require the same regular dialysis treatment regimen. Home PD patients may dialyze on a continuing basis (Continuous Ambulatory Peritoneal Dialysis, or CAPD) or the patients may use a cycler which is a machine that helps the patient to dialyze overnight. Home hemodialysis patients may use the traditional dialysis regimen of three treatments per week, or as is becoming more and more routine, the home hemodialysis patient may be dialyzing more frequently for shorter periods of time. Some home hemodialysis patients may dialyze as often as six times per week, others may be doing five or four days per week. The need that this population has for the proposed services is a function of the individual patient need for dialysis care and treatment.*

…

Dialysis schedules at times which are not convenient for the patient will adversely affect patient compliance and lead to higher missed treatment rates. Home dialysis affords the patient maximum flexibility with scheduling treatment at times which are convenient, and in the patient residence. The patient has total control of the treatment.

Dialysis in a setting which is not convenient for the patient, similarly leads to patient compliance issues and higher missed treatment rates."

On pages 22-23, the applicant states the lease for the current location of INS-H is expiring at the end of 2021 and the facility should relocate at the end of the lease. The applicant states the relocated facility will be located on the same site as a newly-approved vascular access center (Metrolina Vascular Access Care, Project I.D. #F-11612-18) as well as BMA West Charlotte, recently approved by the Agency to be relocated (Project I.D. #F-11827-19, certificate issued March 31, 2020). The applicant states Metrolina Nephrology Associates will also have onsite physician offices. The applicant states the goal is to create a one-stop location where the entire range of services for care for dialysis patients can be accessed.

On pages 24-25, the applicant states:

"…, this is an effort to co-locate the nephrology physician office, the vascular access center, the in-center dialysis center and the home training center. This location will be the first of its kind in North Carolina: a healthcare campus focused on providing care for patients suffering with kidney disease.

The heath care environment is changing. It is becoming increasingly important to recognize the patient experience as a part of the delivery model. Healthcare providers are scored by patients, and these scores become public record. Consider the CMS website Medicare Dialysis Facility Compare. On this website, Medicare identifies the 'Quality of patient care star rating'. This rating model is derived directly from patient feedback.

Fresenius Medical Care, and INS are seeking to ensure continued positive patient satisfaction scores with the services provided. The CMS star rating reported by CMS is not an indication of the quality of care as measured by patient outcomes, but rather is a measure of the perceived patient satisfaction with the dialysis facility. Creation of a 'one stop' location for the myriad services necessary for the dialysis patients is aimed singularly at patient convenience.

The lifestyle of the dialysis patient is continually interrupted by the necessity for dialysis. Creating a center of excellence for the patient recognizes the many times a dialysis patient must travel for medical care. Patients must see the nephrologist. Patients must travel for dialysis (if an in-center patient). Home dialysis patients must travel for home training, and then monthly clinic visits. Patients must travel for dialysis access care from the vascular center. Fresenius Medical Care and INS, working together with Metrolina Nephrology Associates, is seeking to ease the life of the dialysis

> *patient by co-locating this home training center with other centers involved with dialysis patient care. This application is predicated upon patient convenience."*

On page 18, the applicant states that, in July 2019, the President of the United States issued an executive order encouraging greater use of home dialysis for kidney disease patients. The applicant includes a copy of the executive order in Exhibit A.4. The executive order states, in part:

> *"Within 30 days of the date of this order, the Secretary shall select a payment model to evaluate the effects of creating payment incentives for greater use of home dialysis and kidney transplants for Medicare beneficiaries on dialysis. The model should adjust payments based on the percentage of a participating provider's attributed patients who either are on home dialysis or have received a kidney transplant and should include a learning system to help participants improve performance. Greater rates of home dialysis and transplantation will improve quality of life and care for patients who require dialysis…"*

On the same day the executive order was issued, the US Department of Health and Human Services (US DHHS) put out a press release, stating one of its goals in response to the executive order was to have 80 percent of patients receiving either home dialysis or a kidney transplant by 2025.[1]

The applicant states on pages 18-19 that at the end of CY 2018, FMC Charlotte, the predominant facility in Mecklenburg County for home dialysis patients, had 26 HH patients. The applicant states that INS Charlotte and INS-H began offering HH services January 1, 2019, and at the end of CY 2019, there were 33 HH patients among the three facilities (FMC Charlotte, INS Charlotte, and INS-H), which is a growth of 26.9 percent.

On page 25, the applicant states:

> *"…, INS seeks to relocate three additional stations to support the growing number of home hemodialysis patients in the area. As already noted, the home hemodialysis patient population served by Fresenius related facilities in Mecklenburg County increased by more than 26% in 2019. INS expects this is just the beginning of a significant paradigm shift to home dialysis, and specifically home hemodialysis. Consequently more stations are necessary.*
>
> *With only two stations, INS can, in a practical sense, train only two patients per day. With the expected surge in this patient population two stations is not enough. Further complicating this is the reality of home hemodialysis training: not every patient successfully completes the training and goes home to dialyze. Unfortunately some patients are not able to complete the training, or the daily rigors of self dialysis become overwhelming and the patient desires to change to in-center dialysis. INS believes that relocating three additional stations to the relocated facility will ensure sufficient*

[1]https://www.hhs.gov/about/news/2019/07/10/hhs-launches-president-trump-advancing-american-kidney-health-initiative.html (last accessed April 30, 2020)

capacity for the patients desiring to perform home hemodialysis. Training capacity will exist for up to five patients on a continuous basis."

An increase in HH patients is consistent with publicly available data. The Project Analyst reviewed the 2019 United States Renal Data System (USRDS) Annual Data Report.[2] According to the USRDS, the number of patients nationally with End Stage Renal Disease (ESRD) who used HH as their treatment modality has steadily increased since December 2007. Moreover, when reporting the national patient trends for all home treatment modalities from 1996 to 2017, the USRDS states that since 2007, the year with the lowest utilization of home treatment modalities, the number of ESRD patients utilizing home treatment modalities has "increased appreciably." The report further states use of HH treatment for newly diagnosed patients was 120.8 percent higher in 2017 than in 2007. The data tables used by the USRDS in compiling its annual report showed that HH was the modality with the highest growth percentage between 2016 and 2017.

Comments submitted by Piedmont Dialysis Center of Wake Forest University (PDC) during the public comment period suggest that the applicant does not demonstrate a need to relocate three HH training stations to the relocated facility because it only projects to serve one additional HH patient per year. The comments also state the applicant does not demonstrate why patients trained in HH need additional training stations. The Agency notes that demonstration of need, particularly in the absence of a required performance standard, is not necessarily contingent upon projecting to serve a specific number of additional patients, and that there are myriad ways to demonstrate need. The Agency notes the executive order issued by the President of the United States and the goal of US DHHS to have 80 percent of new patients beginning on home dialysis or receiving a transplant by 2025 would be likely to result in a significant increase in the number of home dialysis patients from current levels.

Comments submitted on July 12, 2019 by Wake Forest University Health Sciences (WFUHS), the parent company of PDC, regarding the establishment of new ESRD methodology and performance standards, state:

"The maximum home hemodialysis patients that can be trained on a single home hemodialysis training station per calendar year is six patients. However, that number has been far less in our experience due to the complexity of home hemodialysis. In short, home hemodialysis is hard."

PDC submitted an application, Project I.D. #G-11868-20, for the April 1, 2020 review cycle, seeking to add in-center stations dedicated to HH training and support. On page 33 of that application, PDC states:

"While HH and PD patients dialyzing at home have no need for additional ICH stations or HH dialysis training stations at the ESRD Treatment Facility, those patients do require monthly visits to the dialysis center for support. During those visits, the home patients receive dietetic and social services counseling, required labs, a monthly exam, and if necessary, the patient may require a backup treatment in center."

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[2] https://www.usrds.org/2019/view/Default.aspx (last accessed April 30, 2020)

The information about need for the proposed project is reasonable and adequately supported based on the following analysis:

- The number of HH patients being followed by FMC Charlotte, INS Charlotte, and INS-H increased by 26.9 percent in CY 2019.
- National data supports the trend of growth in the number of HH patients.
- The federal government has begun creating incentives to encourage dialysis facilities to train more new patients on home dialysis modalities.
- The US DHHS has a stated goal of having 80 percent of new dialysis patients receiving a kidney transplant or using home dialysis modalities within the next five years.
- The applicant expects an increase in referrals for home dialysis modalities as the result of the executive order and US DHHS goal.
- INS-H's existing lease is ending at the end of 2021.
- Relocating the existing facility will allow the creation of a one-stop site for dialysis patients to receive all the services they may need in one location.

Projected Utilization

In Section C, page 17, and on Form C in Section Q, the applicant provides historical and projected utilization as illustrated in the following table.

INS-H – Historical and INS-FD – Projected Patient Utilization								
County	Historical (12/31/2019)				Projected (OY 2 – CY 2023)			
	HH Patients		PD Patients		HH Patients		PD Patients	
	# Patients	% Total	# Patients	% Total	# Patients	% Total	# Patients	% Total
Mecklenburg	5	62.50%	20	83.33%	8.75	74.46%	23.58	85.50%
Cabarrus	2	25.00%	2	8.33%	2.00	17.03%	2.00	7.25%
Iredell	1	12.50%	0	0.00%	1.00	8.51%	0.00	0.00%
Lincoln	0	0.00%	2	8.33%	0.00	0.00%	2.00	7.25%
Total	**8**	**100.00%**	**24**	**100.00%**	**11.75**	**100.00%**	**27.58**	**100.00%**

Table may not foot due to rounding.

In Section C, pages 18-20, and in the Form C Utilization subsection of Section Q, the applicant provides the assumptions and methodology it used to project HH and PD patient utilization, which are summarized below.

Home Hemodialysis Patients

- The applicant begins its utilization projections with its HH patient census on December 31, 2019. On that date, the applicant was serving five HH patients from Mecklenburg County and three HH patients from other counties.

- The applicant assumes that the Mecklenburg County HH patient population will grow at an annual rate of 15 percent.

  The Mecklenburg County Five Year Average Annual Change Rate (AACR), as published in the 2020 SMFP, is 4.2 percent. However, the Five Year AACR is calculated based solely on the number of in-center patients at dialysis treatment facilities, and does not account for patients using home treatment modalities.

  On page 19, the applicant states that its HH patient census in Mecklenburg County grew from 26 patients at the end of CY 2018 to 33 patients at the end of CY 2019, or an annual growth rate of 26.9 percent. The applicant states it projects future utilization at an annual growth rate of 15 percent to be realistic but to be more conservative than its recent growth rate.

- The applicant assumes no growth in the HH patient census from other counties, but assumes they will continue to be followed by INS-H due to patient choice and the applicant adds them to the patient census where appropriate.

- The project is scheduled for completion on December 31, 2021. OY1 is CY 2022. OY2 is CY 2023.

In Section C, page 19, and the Form C Utilization subsection of Section Q, the applicant provides the calculations used to arrive at the projected HH patient census for OY1 and OY2 as summarized in the table below.

INS-FD HH Projections	
Starting point of calculations is Mecklenburg County HH patients being served by INS-H as of December 31, 2019.	5
Mecklenburg County patient population is projected forward by one year to December 31, 2020, using the 15% projected annual growth rate.	5 X 1.15 = 5.75
Mecklenburg County patient population is projected forward by one year to December 31, 2021, using the 15% projected annual growth rate.	5.75 X 1.15 = 6.61
The three patients from other counties are added. This is the projected census on January 1, 2021 and the starting census for this project.	6.61 + 3 = 9.91
Mecklenburg County patient population is projected forward by one year to December 31, 2022, using the 15% projected annual growth rate.	6.61 X 1.15 = 7.60
The three patients from other counties are added. This is the projected census on December 31, 2022 (OY1).	7.60 + 3 = 10.60
Mecklenburg County patient population is projected forward by one year to December 31, 2023, using the 15% projected annual growth rate.	7.60 X 1.15 = 8.75
The three patients from other counties are added. This is the projected census on December 31, 2023 (OY2).	8.75 + 3 = 11.75

Peritoneal Dialysis Patients

- The applicant begins its utilization projections by using its PD patient census as of December 31, 2019. On that date, the applicant was serving 20 PD patients from Mecklenburg County and four patients from other counties.

- The applicant projects that the Mecklenburg County PD patient population will grow at the Five Year AACR for Mecklenburg County published in the 2020 SMFP (4.2 percent).

- The applicant assumes no growth in the PD patient census from other counties, but assumes they continue to be followed by INS-H due to patient choice and the applicant adds them to the patient census where appropriate.

- The project is scheduled for completion on December 31, 2021. OY1 is CY 2022. OY2 is CY 2023.

In Section C, page 20, and the Form C Utilization subsection of Section Q, the applicant provides the calculations used to arrive at the projected PD patient census for OY1 and OY2 as summarized in the table below.

INS-FD PD Projections	
Starting point of calculations is Mecklenburg County PD patients being served by INS-H as of December 31, 2019.	20
Mecklenburg County patient population is projected forward by one year to December 31, 2020, using the Five Year AACR (4.2%).	20 X 1.042 = 20.84
Mecklenburg County patient population is projected forward by one year to December 31, 2021, using the Five Year AACR (4.2%).	20.84 X 1.042 = 21.72
The four patients from other counties are added. This is the projected census on January 1, 2021 and the starting census for this project.	21.72 + 4 = 25.72
Mecklenburg County patient population is projected forward by one year to December 31, 2022, using the Five Year AACR (4.2%).	21.72 X 1.042 = 22.63
The four patients from other counties are added. This is the projected census on December 31, 2022 (OY1).	22.63 + 4 = 26.63
Mecklenburg County patient population is projected forward by one year to December 31, 2023, using the Five Year AACR (4.2%).	22.63 X 1.042 = 23.58
The four patients from other counties are added. This is the projected census on December 31, 2023 (OY2).	23.58 + 4 = 27.58

Comments submitted by PDC during the public comment period suggest projected utilization is not reasonable and adequately supported because the applicant does not provide utilization of new home training patients during CY 2019 and includes HH and PD patients that are already trained and receiving support. The comments further imply that the applicant should have provided the number of home patients that have previously required retraining, projected the number of patients that may require retraining in the future, and provided a number of other statistics based on its historical experience.

The Agency notes that in past applications from PDC or other dialysis facilities affiliated with WFUHS, when projecting the growth of HH and PD patients in facilities which already had existing HH and PD programs, the applications used virtually identical assumptions and methodology as in the current application. The Agency further notes that projecting growth in HH and PD patients in the manner used by this applicant has been widely used by this applicant and other applicant and has been accepted by the Agency when all assumptions are reasonable and adequately supported. There is not currently any type of established methodology to calculate how many patients it is possible to train on HH or PD and there is no process for taking into account patients who visit the center once per month for follow-ups. There is nothing in the current application that would cause the Agency to revisit previously accepted assumptions and methodology. Further, the comments from PDC simply suggest the Agency should find the application nonconforming for failing to provide specific information PDC believes should be provided. The comments from PDC do not suggest any other type of assumptions or methodology that should be considered in evaluating the information PDC believes should be provided, and nothing in the comments from PDC make the assumptions and methodology used in this application unreasonable or unsupported.

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

- The applicant projects future utilization based on historical utilization.

- The applicant demonstrates that using an annual growth rate of 15 percent for Mecklenburg County HH patients is reasonable and adequately supported based on historical patient growth.

- The applicant uses the Five Year AACR for Mecklenburg County as published in the 2020 SMFP to project growth of Mecklenburg County PD patients.

Access

In Section C, page 26, the applicant states it has a long history of providing services to medically underserved populations, and that each of its facilities has a patient population comprised of medically underserved people. The applicant further states its corporate policy is to provide services to all patients regardless of any factor that might classify a patient as medically underserved.

In Section L, page 54, 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-FD Projected Payor Mix CY 2023				
Payment Source	**# HH Patients**	**% HH Patients**	**# PD Patients**	**% PD Patients**
Self-Pay	0.01	0.10%	2.44	8.85%
Medicare*	8.20	69.86%	8.80	31.92%
Medicaid*	0.15	1.28%	0.52	1.89%
Commercial Insurance*	2.46	20.98%	11.82	42.87%
Medicare/Commercial	0.64	5.45%	0.00	0.00%
Misc. (including VA)	0.27	2.34%	3.99	14.46%
Total	**11.75**	**100.00%**	**27.58**	**100.00%**

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

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- 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.

C

INS proposes to relocate INS-H to a new location in Mecklenburg County. The applicant also proposes to relocate three existing dialysis stations from Beatties Ford to its new location. Upon completion of the proposed project, the standalone kidney disease treatment center offering training and support exclusively for HH and PD patients will have five dialysis stations and will be renamed INS-FD.

On its ESRD Data Collection Form submitted to the Agency, Beatties Ford indicates it was certified for 39 dialysis stations on December 31, 2019. The current project proposes to relocate three existing stations from Beatties Ford to the new location for INS-H. Upon completion of this project, Beatties Ford will have 36 certified stations.

In Section D, pages 30-31, the applicant explains why it believes the needs of the population presently utilizing the services to be reduced, eliminated, or relocated will be adequately met following completion of the project. With regard to the relocation of INS-H, the applicant states HH and PD patients do not visit the facility for dialysis treatment three times per week; they visit the facility for their training and then return once per month for follow-up. Thus, the existing HH and PD patients will simply go to a different location for their follow-up once per month. With regard to the relocation of three stations from Beatties Ford, the applicant states Beatties Ford could serve up to 144 patients on 36 stations. The applicant states Beatties Ford's patient census was 123 patients on December 31, 2019, and it projects 12 patients will transfer care to FKC Mallard Creek when that project is complete, consistent with the application to develop FKC Mallard Creek (Project I.D. #F-11375-17).

In Section D, page 32, and on Form D in Section Q, the applicant provides projected utilization of BMA Beatties Ford following completion of the proposed project, as shown in the table below.

Beatties Ford Projected Utilization	
	December 31, 2022
Mecklenburg	122
Gaston	2
Lincoln	1
Total	125

In Section D, pages 31-32, and in the Form D Utilization subsection of Section Q, the applicant provides the assumptions and methodology used to project utilization, as discussed below.

- The applicant begins its utilization projections by using its patient census as of December 31, 2019. On that date, the applicant states Beatties Ford was serving 119 patients from Mecklenburg County, three patients from other North Carolina counties, and one patient from another state.

- The applicant projects that the Mecklenburg County patient population will grow at the Five Year AACR for Mecklenburg County published in the 2020 SMFP (4.2 percent).

- The applicant assumes no growth in the patient census from other North Carolina counties, but assumes they continue to dialyze at Beatties Ford by patient choice and the applicant adds them to the patient census where appropriate.

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

- The applicant subtracts 12 patients who are projected to transfer to FKC Mallard Creek when it begins offering services on January 1, 2021, consistent with Project I.D. #F-11375-17.

In Section D, page 32, and on Form D in Section Q, the applicant provides the calculations used to project the patient census at Beatties Ford through December 31, 2022 (the end of OY1 for the proposed project), as summarized in the table below.

Beatties Ford Projections	
Starting point of calculations is Mecklenburg County patients dialyzing at Beatties Ford on December 31, 2019.	119
Mecklenburg County patient population is projected forward by one year to December 31, 2020, using the Five Year AACR (4.2%).	119 X 1.042 = 124.0
The 12 patients projected to transfer to FKC Mallard Creek are subtracted from the patient population on January 1, 2021.	124.0 – 12 = 112.0
Mecklenburg County patient population is projected forward by one year to December 31, 2021, using the Five Year AACR (4.2%).	112.0 X 1.042 = 116.7
The three patients from other counties are added. This is the projected census on December 31, 2021.	116.7 + 3 = 119.7
Mecklenburg County patient population is projected forward by one year to December 31, 2022, using the Five Year AACR (4.2%).	116.7 X 1.042 = 121.6
The three patients from other counties are added. This is the projected census on December 31, 2022 (the end of OY1).	121.6 + 3 = 124.6

If the applicant did not add any additional dialysis stations to Beatties Ford, it would project to serve 125 patients on 36 stations, which is 3.47 patients per station per week (125 patients / 36 stations = 3.47), for a utilization rate of 86.8 percent by the end of OY1.

On page 32, the applicant states the 2020 SMFP shows Beatties Ford has a facility need for up to seven stations. The applicant states it will submit an application to develop those seven stations for the April 1, 2020 review cycle (see Project I.D. #F-11871-20), for a total of 43 stations upon completion of this project and Project I.D. #F-11871-20. The applicant states that, if the application is approved and the stations are developed by December 31, 2020, it could meet the required performance standard promulgated in Temporary Rule 10A NCAC 14C .2203(b), requiring the applicant to reasonably project to serve 2.8 patients per station per week by the end of the first operating year. Serving 125 patients on 43 stations is 2.91 patients per station per week (125 patients / 43 stations = 2.91).

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

- The applicant uses the Five Year AACR for Mecklenburg County as published in the 2020 SMFP to project patient utilization.
- The applicant accounts for patients who are proposed to transfer care to a different facility as part of projects under development.
- The applicant does not project growth in the patient population residing outside of Mecklenburg County.
- The applicant demonstrates it can reasonably project to serve enough patients to add seven stations pursuant to the facility need published in the 2020 SMFP.

In Section D, page 33, the applicant states each of its facilities has a patient population comprised of medically underserved people and that its corporate policy is to provide services

to all patients regardless of any factor that might classify a patient as medically underserved. The applicant further states the relocation will not impact the patients dialyzing at the facility and existing and new patients will continue to have the same access to care.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the applicant adequately demonstrates that:

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

- The project will not adversely impact the ability of underserved groups to access these services following project completion.

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

CA

INS proposes to relocate INS-H to a new location in Mecklenburg County. The applicant also proposes to relocate three existing dialysis stations from Beatties Ford to its new location. Upon completion of the proposed project, the standalone kidney disease treatment center offering training and support exclusively for HH and PD patients will have five dialysis stations and will be renamed INS-FD.

In Section E, page 35, the applicant states there were no alternatives to the proposed project. The applicant states that its current lease is expiring, and it has to relocate in order to continue to offer services. The applicant further states that, due to the recent executive order from the President and increases in referrals for HH training and support, maintaining two dialysis stations is not sufficient for the patients proposed to utilize this facility.

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

- The application is conforming to all statutory and regulatory review criteria.

- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

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

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

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

2. **Pursuant to Policy ESRD-2, Independent Nephrology Services, Inc. shall relocate INS Huntersville to a new location in Mecklenburg County, rename the facility to INS Freedom Lake, and relocate no more than three dialysis stations from BMA Beatties Ford to INS Huntersville for a total of no more than five dialysis stations at INS Freedom Lake.**

3. **Independent Nephrology Services, Inc. shall install plumbing and electrical wiring through the walls for no more than five dialysis stations which shall include any isolation stations.**

4. **Upon completion of this project, Fresenius Medical Care Holdings, Inc. shall take the necessary steps to decertify three dialysis stations at BMA Beatties Ford for a total of no more than 36 dialysis stations at BMA Beatties Ford following project completion.**

5. **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

INS proposes to relocate INS-H to a new location in Mecklenburg County. The applicant also proposes to relocate three existing dialysis stations from Beatties Ford to its new location. Upon completion of the proposed project, the standalone kidney disease treatment center offering training and support exclusively for HH and PD patients will have five dialysis stations and will be renamed INS-FD.

Capital and Working Capital Costs

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

Construction Contract	$1,586,803
Architect/Engineering Fees	$142,812
Non-Medical Equipment	$8,399
Furniture	$151,122
Contingency	$86,481
Total	$1,975,617

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

In Section F, page 37, the applicant states that there are no projected working capital costs because it is an existing facility that is already operational.

Availability of Funds

In Section F, pages 36-37, the applicant states it will fund the capital cost of the proposed project with accumulated reserves from FMC. Exhibit F-2 contains a letter from the Senior Vice President and Treasurer of FMC, authorizing the use of accumulated reserves for the capital needs of the project. The letter also states that the 2019 accounting for FMC had not yet been completed, but that as of December 31, 2018, FMC had adequate cash and assets to fund the capital cost of the proposed project.

Financial Feasibility

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

Projected Revenues and Operating Expenses		
INS-FD	**FY 1 – CY 2022**	**FY 2 – CY 2023**
Total Treatments	5,369	5,665
Total Gross Revenues (Charges)	$33,778,903	$35,638,675
Total Net Revenue	$3,275,691	$3,433,713
Average Net Revenue per Treatment	$610	$606
Total Operating Expenses (Costs)	$2,188,182	$2,255,122
Average Operating Expense per Treatment	$408	$398
Net Income/(Loss)	**$1,087,509**	**$1,178,591**

Comments submitted by PDC during the public comment period suggest the application should have included separate revenue assumptions or calculations for existing HH or PD patients

who require retraining. The Agency notes there is no such requirement to distinguish sources of revenue as suggested by PDC.

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
- Written comments

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

INS proposes to relocate INS-H to a new location in Mecklenburg County. The applicant also proposes to relocate three existing dialysis stations from Beatties Ford to its new location. Upon completion of the proposed project, the standalone kidney disease treatment center offering training and support exclusively for HH and PD patients will have five dialysis stations and will be renamed INS-FD.

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."* 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 2020 SMFP, there are eight facilities located in Mecklenburg County which are currently providing home dialysis training and support. Information on all seven of these facilities is provided in the table below.

Mecklenburg County Facilities with Home Dialysis Patients as of December 31, 2018				
Dialysis Facility	**Owner**	**# HH Patients**	**# PD Patients**	**Total # Patients**
INS Charlotte*	FMC	0	18	18
INS Huntersville*	FMC	0	9	9
FMC Charlotte	FMC	26	53	79
FMC Southwest Charlotte	FMC	3	6	9
Carolinas Medical Center	Atrium	0	6	6
Charlotte East Dialysis	DaVita	18	40	58
DSI Charlotte Latrobe Dialysis	DSI	9	8	17
DSI Glenwater Dialysis	DSI	2	5	7

Source: Table 9A of the 2020 SMFP.
*Standalone facilities offering exclusively home training and support

In Section G, page 42, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Mecklenburg County. The applicant states that the proposed project does not involve creating any new dialysis stations in Mecklenburg County.

In Section C, pages 22-25, the applicant states the facility must relocate at the end of the facility's existing lease. Additionally, on page 24, the applicant states:

> *"…, this is an effort to co-locate the nephrology physician office, the vascular access center, the in-center dialysis center and the home training center. This location will be the first of its kind in North Carolina: a healthcare campus focused on providing care for patients suffering with kidney disease."*

The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

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

- The proposal would not result in an increase in the number of dialysis stations in Mecklenburg County.
- The applicant adequately demonstrates the stations proposed to be relocated from Beatties Ford are needed at INS-H.
- The applicant adequately demonstrates the existing facility needs to be relocated.
- The applicant adequately demonstrates the location of the relocated and expanded facility will create the first dialysis services campus in North Carolina.

<u>Conclusion</u>

The Agency reviewed the:

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

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

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

C

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

INS-H Current and INS-FD Projected Staffing			
	Current	**To Be Added**	**Projected – CYs 2022 & 2023**
Administrator	1.00	0.00	1.00
Home Training Nurses	2.00	2.00	4.00
Patient Care Technicians	2.00	1.50	3.50
Dietician	0.50	0.00	0.50
Social Worker	0.50	0.00	0.50
Maintenance	0.33	0.00	0.33
Administrative/Bus. Office	0.25	0.75	1.00
FMC Director Operations	0.20	0.00	0.20
In-Service	0.15	0.00	0.15
Chief Technician	0.10	0.00	0.10
Total	**7.03**	**4.25**	**11.28**

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.4, which is found in Section Q. In Section H, page 43, the applicant describes the methods it uses to recruit or fill new positions and its existing training and continuing education programs. In Section H, page 44, the applicant identifies the current medical director. In Exhibit H-4, the applicant provides a letter from the current medical director indicating her support for the proposed project and her intent to continue serving as medical director for the facility.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section I, page 45, the applicant states that the following ancillary and support services are necessary for the proposed services, and explains how each ancillary and support service is made available:

INS-FD – Ancillary and Support Services	
Services	**Provider**
Self-care training (in-center)	On site
Home training HH PD Accessible follow-up program	 On site On site On site
Psychological counseling	Referral to Cardinal Innovations or Blue Moon Counseling
Isolation – hepatitis	On site
Nutritional counseling	On site
Social Work services	On site
Acute dialysis in an acute care setting	Referral to Carolinas Medical Center
Emergency care	Provided on site by staff until ambulance arrival
Blood bank services	Referral to Carolinas Medical Center
X-ray, diagnostic, & evaluation services	Referral to Carolinas Medical Center
Laboratory services	On site
Pediatric nephrology	Referral to Carolinas Medical Center
Vascular surgery	Referral to Metrolina Vascular Access Center, Carolinas Medical Center, or Novant Health Presbyterian Medical Center
Transplantation services	Referral to Carolinas Medical Center
Vocational rehabilitation & counseling	Referral to Vocational Rehabilitation of Mecklenburg County
Transportation	Mecklenburg Transportation Services

The applicant provides supporting documentation in Exhibits I-1 through I-4.

In Section I, page 46, the applicant describes its existing and proposed relationships with other local health care and social service providers.

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

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 48, the applicant states that the project involves constructing 9,066 square feet of new space as part of a medical office building. Line drawings are provided in Exhibit K-1.

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

On page 49, 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. The applicant states all additional costs will be the responsibility of INS and will not be passed on to patients.

On pages 49-50, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

On pages 50-51, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal, and power at the site. The applicant 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;

C

In Section L, page 53, the applicant provides the historical payor mix during CY 2018 for its existing services, as shown in the table below. The applicant states that as of the date of the filing of this application, financial accounting for CY 2019 was not yet complete, and that INS-H was not certified for HH in CY 2018.

INS-H Historical Payor Mix CY 2018		
Payment Source	**# PD Patients**	**% PD Patients**
Self-Pay	0.80	8.85%
Medicare*	2.87	31.92%
Medicaid*	0.17	1.89%
Commercial Insurance*	3.86	42.87%
Medicare/Commercial	0.00	0.00%
Misc. (including VA)	1.30	14.46%
Total	**9.00**	**100.00%**

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

In Section L, page 52, the applicant provides the following comparison.

INS-H	% of Patients Served During CY 2019	Percentage of the Population of Mecklenburg County
Female	50.0%	51.9%
Male	50.0%	48.1%
Unknown	0.0%	0.0%
64 and Younger	90.9%	88.8%
65 and Older	9.1%	11.2%
American Indian	0.0%	0.8%
Asian	4.5%	6.4%
Black or African-American	59.1%	32.9%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	18.2%	46.4%
Other Race	18.2%	13.4%
Declined / Unavailable	0.0%	0.0%

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 handicapped persons 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, the applicant states in Section L, page 54, that it has no obligation by any of its facilities to provide uncompensated care or community service under any federal regulations.

In Section L, page 54, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 54, 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-FD Projected Payor Mix CY 2023				
Payment Source	**# HH Patients**	**% HH Patients**	**# PD Patients**	**% PD Patients**
Self-Pay	0.01	0.10%	2.44	8.85%
Medicare*	8.20	69.86%	8.80	31.92%
Medicaid*	0.15	1.28%	0.52	1.89%
Commercial Insurance*	2.46	20.98%	11.82	42.87%
Medicare/Commercial	0.64	5.45%	0.00	0.00%
Misc. (including VA)	0.27	2.34%	3.99	14.46%
Total	**11.75**	**100.00%**	**27.58**	**100.00%**

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

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 69.86 percent of HH services and 31.92 percent of PD services will be provided to Medicare patients and 1.28 percent of HH services and 1.89 percent of PD services will be provided to Medicaid patients.

On page 55, 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 for the following reasons:

- The projected PD payor mix is based on historical PD payor mix.

- The projected HH payor mix is based on historical HH mix at Fresenius facilities in western North Carolina because INS-H did not have sufficient historical HH payor mix to make reasonable projections.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 55, the applicant adequately describes the range of means by which patients will have access to 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.

(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 57, 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.

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

INS proposes to relocate INS-H to a new location in Mecklenburg County. The applicant also proposes to relocate three existing dialysis stations from Beatties Ford to its new location. Upon completion of the proposed project, the standalone kidney disease treatment center offering training and support exclusively for HH and PD patients will have five dialysis stations and will be renamed INS-FD.

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."* 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 2020 SMFP, there are eight facilities located in Mecklenburg County which are currently providing home dialysis training and support. Information on all seven of these facilities is provided in the table below.

Mecklenburg County Facilities with Home Dialysis Patients as of December 31, 2018				
Dialysis Facility	**Owner**	**# HH Patients**	**# PD Patients**	**Total # Patients**
INS Charlotte*	FMC	0	18	18
INS Huntersville*	FMC	0	9	9
FMC Charlotte	FMC	26	53	79
FMC Southwest Charlotte	FMC	3	6	9
Carolinas Medical Center	Atrium	0	6	6
Charlotte East Dialysis	DaVita	18	40	58
DSI Charlotte Latrobe Dialysis	DSI	9	8	17
DSI Glenwater Dialysis	DSI	2	5	7

Source: Table 9A of the 2020 SMFP.
*Standalone facilities offering exclusively home training and support

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 58, the applicant states:

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

Regarding the impact of the proposal on cost effectiveness, in Section N, page 59, the applicant states:

> *"The relocation is intended to enhance the patient experience, and locates home dialysis training services at the new healthcare campus intended to support patients with chronic kidney disease. Approval of this application will allow the facility to expand its home training capacity and serve more patients who are being referred for home dialysis. This is a significantly positive impact to the patients of the area."*

Regarding the impact of the proposal on quality, in Section N, page 59, 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 provide 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 59, the applicant states it has a long history of providing services to medically underserved populations, and that each of its facilities has a patient population comprised of medically underserved people. The applicant further states its corporate policy is to provide services to all patients regardless of any factor that might classify a patient as medically 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, K, 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, D, 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 for 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

On Form A 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 dialysis facilities located in North Carolina.

In Section O, page 64, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents related to quality of care 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.

(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 relocate the existing facility, which serves exclusively HH and PD patients, to a new location and to relocate three dialysis stations from Beatties Ford. The Criteria and Standards for End State Renal Disease Services promulgated in 10A NCAC 14C .2200 do not apply to facilities that do not have in-center patients.