ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

Decision Date: January 14, 2019
Findings Date: January 14, 2019

Project Analyst: Julie M. Faenza
Team Leader: Fatimah Wilson

Project ID #: F-11637-18
Facility: INS Charlotte
FID #: 070499
County: Mecklenburg
Applicant: Independent Nephrology Services, Inc.
Project: Relocate two dialysis stations from BMA Beatties Ford resulting in a freestanding kidney disease treatment center offering training and support exclusively for patients dialyzing at home upon project completion

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. (INS) proposes to relocate two dialysis stations from BMA Beatties Ford to INS Charlotte, an existing standalone kidney disease treatment center offering peritoneal dialysis (PD) training and support. The two stations will be used exclusively for home hemodialysis (HH) patient training and support. At project completion, INS Charlotte will be a standalone kidney disease treatment center offering training and support exclusively for PD and HH patients dialyzing at home.

Need Determination

The applicant does not propose to increase the number of licensed beds in any category, add any new health services, or acquire equipment for which there is a need determination in the

2018 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations in the 2018 SMFP that are applicable to this review.

Policies

There is one policy in the 2018 SMFP which is applicable to this review:

Policy ESRD-2: Relocation of Dialysis Stations, on page 27 of the 2018 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 Semiannual Dialysis Report, and*
>
> 2. *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 Semiannual Dialysis Report."*

Both INS Charlotte and BMA Beatties Ford are located 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 for the reasons stated above.

(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 two dialysis stations from BMA Beatties Ford to INS Charlotte. The two stations will be used exclusively for HH patient training and support. At project completion, INS Charlotte will be a standalone kidney disease treatment center offering training and support exclusively for PD and HH patients dialyzing at home.

INS Charlotte 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 are currently no stations at the existing facility.

INS proposes to relocate two existing dialysis stations from BMA Beatties Ford to INS Charlotte in order to offer home hemodialysis (HH) training and support in addition to the existing PD training and support, creating a freestanding facility dedicated to training and support exclusively for home dialysis modalities. Previous attempts to create this type of facility were unsuccessful due to the performance standard promulgated in 10A NCAC 14C .2203, requiring that dialysis stations and kidney disease treatment facilities needed a utilization rate of at least 3.2 patients per station per week (or needed to reasonably project that rate of utilization) prior to developing new stations. 10A NCAC 14C .2203 does not distinguish between in-center stations and stations used exclusively for HH patient training and support. A patient dialyzing in an in-center setting typically receives treatment three times per week, with each treatment lasting approximately four hours, allowing for multiple patients to use the same station within the same day. In Section C, pages 25-26, the applicant describes the training schedule for HH patients, and states that HH patients typically go through four training treatments per week, with each treatment lasting approximately six hours. The applicant states that the average number of training sessions a prospective HH patient receives is 25, which lasts 6-7 weeks. The applicant states that the training schedule for HH patients does not allow for more than one patient to use the station for the 6-7 weeks that training takes. Thus, it is impossible for a station being used exclusively for HH patient training and support to meet the performance standard promulgated in 10A NCAC 14C .2203.

On August 8, 2018, Fresenius Medical Care Holdings, Inc. (FMC) – the parent company of INS, as well as the parent company of other dialysis facility operators – 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.

Patient Origin

On page 365, the 2018 SMFP defines the service area for dialysis stations as *"…the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area."* Thus, the service area is Mecklenburg County. Facilities may serve residents of counties not included in their service area.

The following table illustrates current and projected patient origin.

INS Charlotte – Current and Projected Patient Origin						
	Historical (6/30/2018)			Projected (Operating Year 2)		
County	# of HH Patients	# of PD Patients	% of Total	# of HH Patients	# of PD Patients	% of Total
Mecklenburg	0	10	83.3%	6	11	90.1%
Anson	0	1	8.3%	0	1	5.0%
Gaston	0	1	8.3%	0	1	5.0%
Total	**0**	**12**	**100.0%**	**6**	**13**	**100.0%**

Table may not foot due to rounding.
Source: Section C, pages 16 and 24

In Section C, pages 16-19, 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 16-20, 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 20, 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 frequent, 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.

Approval of this application will allow INS to relocate two home hemodialysis stations to be used for home training and support program of patients choosing hemodialysis. This will enhance patient training opportunities and ultimately will allow INS Charlotte to enable more patients to dialyze at home in a convenient setting, at times which are convenient for the patient."

In the discussion about projected utilization, on pages 17-18, the applicant states that between December 31, 2013 and June 30, 2018, the HH patient population being served at FMC Charlotte (the facility with the most home treatment patients in Mecklenburg County that is owned and/or operated by the applicant or an affiliated entity) grew at an overall rate of 135.7 percent, or by an annual average of 30.16 percent. The applicant further states that when it considers only Mecklenburg County HH patients being served at FMC Charlotte, the number of patients grew by 107.7 percent during the same time period, or by an annual average of 23.93 percent.

This is consistent with publicly available data. The Project Analyst reviewed the 2018 United States Renal Data System (USRDS) Annual Data Report.[1] 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 2006. Moreover, when reporting the national patient trends for all home treatment modalities from 1996 to 2016, 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."

In Exhibit C-1, the applicant provides five letters of support from Mecklenburg County patients currently receiving training and support for HH through FMC Charlotte, all of who indicated they would consider transferring to INS Charlotte once services are available.

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

- The applicant adequately explains the need patients have for HH training and support programs.

- The applicant provides historical utilization data which support the need the patient population has for the proposed services.

- The applicant's historical utilization data are consistent with available national data.

[1] https://www.usrds.org/2018/view/Default.aspx (last accessed January 4, 2019)

- The applicant provides letters of support from current patients who will consider transferring to INS Charlotte for the proposed services.

Projected Utilization

In Section C, pages 16 and 24, the applicant provides historical and projected utilization as illustrated in the following table.

INS Charlotte – Current and Projected Utilization						
	Historical (6/30/2018)			Projected (Operating Year 2)		
County	# of HH Patients	# of PD Patients	% of Total	# of HH Patients	# of PD Patients	% of Total
Mecklenburg	0	10	83.3%	6	11	90.1%
Anson	0	1	8.3%	0	1	5.0%
Gaston	0	1	8.3%	0	1	5.0%
Total	**0**	**12**	**100.0%**	**6**	**13**	**100.0%**

Table may not foot due to rounding.

In Section C.1, pages 16-19, 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 by assuming that the five Mecklenburg County HH patients who provided letters of support for the project will transfer to INS Charlotte upon project completion.

- The applicant assumes that the Mecklenburg County HH patient population will grow at an annual rate of 15.91 percent.

  The Mecklenburg County Five Year Average Annual Change Rate (AACR), as published in the July 2018 Semiannual Dialysis Report (SDR), is 3.9 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 17, the applicant states that based on the data collection forms it has submitted to the Agency, the HH patient population being served at FMC Charlotte (the facility with the most home treatment patients in Mecklenburg County that is owned and/or operated by the applicant or an affiliated entity) grew at an overall rate of 135.7 percent, or by an annual average of 30.16 percent. The applicant's data is shown in the table below. The Project Analyst calculated average rates of change in the same table below the applicant's data.

HH Patient Population – FMC Charlotte							
	12/31/13	**12/31/14**	**12/31/15**	**12/31/16**	**12/31/17**	**6/30/18**	**Annual Average***
Mecklenburg	13	22	23	24	16	27	
Cabarrus	0	2	1	1	1	1	
Gaston	0	0	1	1	0	0	
Union	1	1	1	3	3	2	
South Carolina	0	0	2	3	3	3	
Total	**14**	**25**	**28**	**32**	**23**	**33**	
Change (Total)	--	78.6%	12.0%	14.3%	-28.1%	43.5%	26.7%
Change (Meck.)	--	69.2%	4.5%	4.3%	-33.3%	68.8%	25.2%

*The Project Analyst calculated the annual average by using the same method as shown on page 18 of the application – sum the total percent of change; divide by the number of months (54), and then multiply by 12 to get the yearly average.

The Project Analyst's calculations yield slightly different results than the applicant's, but both sets of calculations demonstrate that the average annual growth in the HH population for FMC Charlotte and Mecklenburg County HH patients receiving support from FMC Charlotte is higher than the Five Year AACR of 3.9 percent that is published in the July 2018 SDR.

On pages 17-18, the applicant states that it proposes to use an average growth rate of 15.91 percent, which it states is the average based on the last 30 months of data. The Project Analyst verified that a growth rate of 15.91 percent annually over the last 30 months is consistent with the applicant's data.

- The project is scheduled for completion on December 31, 2019. OY1 is CY 2020. OY2 is CY 2021.

In Section C, page 19, 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 Charlotte HH Projections	
Starting point of calculations is Mecklenburg County patients willing to transfer their care to INS Charlotte as of December 31, 2019. This is the starting census for the project.	5
Mecklenburg County patient population is projected forward by one year to December 31, 2020, using the applicant's 15.91 percent growth rate. This is the projected census on December 31, 2020 (OY1).	5 X 1.1591 = 5.8
Mecklenburg County patient population is projected forward by one year to December 31, 2020, using the applicant's 15.91 percent growth rate. This is the projected census on December 31, 2021 (OY2).	5.8 X 1.1591 = 6.7

Peritoneal Dialysis Patients

- The applicant begins its utilization projections by using its PD patient census as of June 30, 2018.

- The applicant projects that the Mecklenburg County PD population will grow at the Five Year AACR for Mecklenburg County published in the July 2018 SDR (3.9 percent).

- The applicant assumes no population growth for the patients who utilize PD services at INS Charlotte and live in other counties, but adds the patients to the calculations when appropriate.

- The project is scheduled for completion on December 31, 2019. OY1 is CY 2020. OY2 is CY 2021.

In Section C, page 19, the applicant provides the calculations it uses to arrive at the projected PD patient census for OY1 and OY2 as summarized in the table below.

INS Charlotte PD Patients	
Starting point of calculations is Mecklenburg County PD patients dialyzing at INS Charlotte on June 30, 2018.	10
Mecklenburg County patient population is projected forward by six months to December 31, 2018, using one half of the Five Year AACR (3.9%).	10 X 1.0195 = 10.2
Mecklenburg County patient population is projected forward by one year to December 31, 2019, using the Five Year AACR (3.9%).	10.2 X 1.039 = 10.6
The patients from other counties and states are added. This is the projected census on December 31, 2019 and the starting census for this project.	10.6 + 2 = 12.6
Mecklenburg County patient population is projected forward by one year to December 31, 2020, using the Five Year AACR (3.9%).	10.6 X 1.039 = 11.0
The patients from other counties and states are added. This is the projected census on December 31, 2020 (OY1).	11.0 + 2 = 13.0
Mecklenburg County patient population is projected forward by one year to December 31, 2021, using the Five Year AACR (3.9%).	11.0 X 1.039 = 11.4
The patients from other counties and states are added. This is the projected census on December 31, 2021 (OY2).	11.4 + 2 = 13.4

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 15.91 percent for Mecklenburg County HH patients is reasonable and adequately supported.

- The applicant uses the Five Year AACR for Mecklenburg County as published in the July 2018 SDR to project growth of Mecklenburg County PD patients.

- The applicant does not project growth for its patients who do not reside in Mecklenburg County.

Access

In Section C, page 20, 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, or any other factor that would classify a patient as underserved."*

In Section L, page 66, 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 Charlotte Projected Payor Mix CY 2021			
Payment Source	**% Total Patients**	**% HH Patients**	**% PD Patients**
Self-Pay/Indigent/Charity	4.76%	2.25%	1.59%
Medicare	42.86%	61.63%	45.24%
Medicaid	4.76%	2.74%	3.83%
Commercial Insurance	33.33%	33.38%	35.41%
Medicare/Commercial	4.76%	0.00%	6.46%
Misc. (including VA)	9.52%	0.00%	7.46%
Total	**100.00%**	**100.00%**	**100.00%**

The projected payor mix is reasonable and adequately supported.

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.

C

INS proposes to relocate two dialysis stations, to be used exclusively for HH patient training and support, from BMA Beatties Ford to INS Charlotte.

According to the July 2018 SDR, BMA Beatties Ford had 32 certified stations as of December 31, 2017. In projects that were previously approved but not yet fully developed as of December 31, 2018, BMA Beatties Ford was approved to add a total of 11 stations:

- Project I.D. #F-10259-14 (add seven stations)

- Project I.D. #F-11007-15 (add four stations)

Additionally, on November 15, 2018, the applicant submitted Project I.D. #F-11638-18, at the same time as this application, proposing to relocate two stations from BMA Beatties Ford to INS Huntersville. That project is approved as of the same date of these findings.

As of the date of these findings, BMA Beatties Ford has 32 certified stations. At the completion of the two previously approved but not yet developed projects, BMA Beatties Ford will have 43 certified stations. The applicant proposes to relocate two stations to INS Charlotte as part of this project, and simultaneously proposes to relocate two stations to INS Huntersville as part of Project I.D. #F-11638-18. Upon completion of this project and and all affiliated projects, BMA Beatties Ford will have 39 certified stations.

In Section D, page 33, 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. On page 33, the applicant states that the relocation will not have any adverse effect on patient access.

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

BMA Beatties Ford Projected Utilization	
	December 31, 2019
# Patients	112

In Section D, pages 31-32, the applicant provides the assumptions and methodology used to project utilization, as discussed below.

- The applicant states that there were 118 patients dialyzing at BMA Beatties Ford on June 30, 2018. 115 of those patients were Mecklenburg County residents, two patients are from Gaston County, and one patient is from another state.

- The applicant assumes that the patient from another state who was dialyzing at BMA Beatties Ford as of June 30, 2018 is a transient patient and does not include that patient in future utilization calculations.

- The applicant projects that the Mecklenburg County patient population of BMA Beatties Ford will grow at a rate of 3.9 percent, which is the Five Year AACR for Mecklenburg County as published in the July 2018 SDR.

- The applicant projects no growth for patients residing in Gaston County, but adds those patients to the calculations where appropriate.

- The applicant states that as part of Project I.D. #F-11375-17 (develop a new 12-station dialysis facility, FKC Mallard Creek), it projects 12 patients from BMA Beatties Ford will transfer care to FKC Mallard Creek once it opens and subtracts those 12 patients from the calculations as of December 31, 2019 (the projected completion date for FKC Mallard Creek).

- The applicant states that it assumes Project I.D. #F-11638-18 will be approved, and subtracts those two stations from the calculations where appropriate.

In Section D, page 32, and in supplemental information, the applicant provides the calculations it uses to arrive at the projected patient census at BMA Beatties Ford for OY1 and OY2 of the proposed project, as summarized in the table below.

BMA Beatties Ford Patients	
Starting point of calculations is the 115 Mecklenburg County patients dialyzing at BMA Beatties Ford on June 30, 2018, and is the starting census for this project.	115
Mecklenburg County patient population is projected forward by six months to December 31, 2018, using one half of the Five Year AACR of 3.9%.	115 X 1.0195 = 117.2
Mecklenburg County patient population is projected forward by one year to December 31, 2019, using the Five Year AACR of 3.9%.	117.2 X 1.039 = 121.8
The 12 patients projected to transfer care to FKC Mallard Creek upon project completion are subtracted from the Mecklenburg County patient population dialyzing at BMA Beatties Ford.	121.8 – 12 = 109.8
The patients from Gaston County are added. This is the projected census at the start of OY1.	109.8 + 2 = 111.8
Mecklenburg County patient population is projected forward by one year to December 31, 2020, using the Five Year AACR of 3.9%.	109.8 X 1.039 = 114.1
The patients from Gaston County are added. This is the projected census on December 31, 2020 (end of OY1).	114.1 + 2 = 116.1
Mecklenburg County patient population is projected forward by one year to December 31, 2021, using the Five Year AACR of 3.9%.	114.1 X 1.039 = 118.5
The patients from Gaston County are added. This is the projected census on December 31, 2021 (end of OY2).	118.5 + 2 = 120.5

The applicant rounds up and projects to serve 117 patients on 39 stations, which is 3.0 patients per station per week (117 patients / 39 stations = 3.0), for a utilization rate of 75.0 percent by the end of OY1, and 121 patients on 39 stations, which is 3.1 patients per station per week (121 patients / 39 stations = 3.1), for a utilization rate of 77.5 percent, by the end of OY2.

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 July 2018 SDR 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 accounts for stations that are proposed to be relocated as part of projects under development.

In Section D, page 33, the applicant states that the proposed relocation of stations will have no effect on the ability of patients using the existing facility, including low income patients, women, disabled patients, and other underserved patients, to access services, and states that it makes dialysis services available to all residents of the service area without qualification.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- 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 two dialysis stations, to be used exclusively for HH patient training and support, from BMA Beatties Ford to INS Charlotte.

In Section E, page 34, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo: the applicant states that maintaining the status quo would result in the inability to offer HH training at INS Charlotte. Therefore, this is not an effective alternative.

- Relocate a Different Number of Stations: the applicant states that based on the projected patient population, one station would not be sufficient, and more than two stations would be excessive. Therefore, this is not an effective alternative.

- Develop a New Standalone Home Training Facility: the applicant states that development of a new standalone home training facility would require significant capital expenditures. Therefore, this is not an effective alternative.

On pages 34-35, the applicant states that its proposal is the most effective alternative because it is the most cost effective option and is necessary to meet the need for a convenient location for patients to receive HH training and support in Mecklenburg County.

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
- Supplemental information requested by the Agency
- 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 and any supplemental responses. In the event that representations conflict, Independent Nephrology Services, Inc. shall materially comply with the last made representation.**

2. **Pursuant to Policy ESRD-2, Independent Nephrology Services, Inc. shall relocate two dialysis stations from BMA Beatties Ford to INS Charlotte.**

3. **Independent Nephrology Services, Inc. shall install plumbing and electrical wiring through the walls for no more than two 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 two dialysis stations at BMA Beatties Ford for a total of no more than 39 dialysis stations at BMA Beatties Ford following completion of this project, Project I.D. #F-10259-14 (add seven stations), Project I.D. #F-11007-15 (add four stations), and Project I.D. #F-11638-18 (relocate two stations to INS Huntersville).**

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 two dialysis stations, to be used exclusively for HH patient training and support, from BMA Beatties Ford to INS Charlotte.

Capital and Working Capital Costs

In Section F.1, page 36, the applicant projects no capital costs. In Sections F.10 and F.11, page 39, the applicant states that there are no projected start-up expenses or initial operating expenses because it is an existing facility that is already operational.

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 B, the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

Projected Revenues and Operating Expenses		
INS Charlotte	**Operating Year 1 CY 2020**	**Operating Year 2 CY 2021**
Total Treatments	2,519	2,815
Total Gross Revenues (Charges)	$10,045,772	$11,226,220
Total Net Revenue	$1,449,295	$1,607,940
Average Net Revenue per Treatment	$575	$571
Total Operating Expenses (Costs)	$1,195,687	$1,263,752
Average Operating Expense per Treatment	$475	$449
Net Income/Profit	**$253,608**	**$344,188**

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs, and charges. See Section R 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 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 two dialysis stations, to be used exclusively for HH patient training and support, from BMA Beatties Ford to INS Charlotte.

On page 365, the 2018 SMFP defines the service area for dialysis stations as *"…the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area."* Thus, the service area is Mecklenburg County. Facilities may serve residents of counties not included in their service area.

According to Table C of the July 2018 SDR, there are eight facilities which provide home dialysis training and support in Mecklenburg County. Information on all eight of these facilities, from Table C of the July 2018 SDR, is provided below:

Mecklenburg County Home Dialysis Patients
Facilities with Home Dialysis Patients as of December 31, 2017

Dialysis Facility	Owner	# HH Patients	# PD Patients	Total # Patients
INS Charlotte*	Fresenius	0	13	13
INS Huntersville*	Fresenius	0	7	7
FMC Charlotte	Fresenius	23	55	78
FMC Southwest Charlotte	Fresenius	2	8	10
Carolinas Medical Center	CMC	0	5	5
Charlotte East Dialysis	DaVita	20	35	55
DSI Charlotte Latrobe Dialysis	DSI	2	8	10
DSI Glenwater Dialysis	DSI	3	7	10

Source: July 2018 SDR, Table C.
*Standalone facilities offering exclusively home training and support

In Section G, pages 46-48, 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:

> *"Approval of this application will not create new dialysis stations or facilities in Mecklenburg County, but rather allows the INS Charlotte facility to offer home hemodialysis training and support services.*
>
> *INS notes several facts about the Mecklenburg County and the ESRD patient population:*
>
> 1. *Mecklenburg County has the largest ESRD patient population of any county in North Carolina. The July 2018 SDR reports that as of December 31, 2017 there*

were 1,710 dialysis patients residing in Mecklenburg County. This is equiavlent [sic] *to 9.48% of the total ESRD patient population of NC.*

2. *There were 168 patients* [sic] *home dialysis patients in Mecklenburg County. This is only 9.8% of the 1,710 dialysis patients residing in Mecklenburg County.*

…

4. *Table A of the SDR indicates there were 18 operational facilities in Mecklenburg County* [as of December 31, 2017]*. … When considering the INS facilities, there are* [currently] *23 operational dialysis facilities.*

5. *Only two facilities are dedicated exclusively to home dialysis: INS Charlotte and INS Huntersville.*

6. *Table C of the July 2018 SDR provides information for the facilities providing home dialysis training and support. Eight Mecklenburg County dialysis facilities provide home training and support. Only five offer home hemodialysis.*

…

The above discussion does provide an indication of the limited locations offering home hemodialysis training and support.

…

INS does not believe that this proposal will unnecessarily duplicate any existing services within Mecklenburg County."

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 applicant adequately demonstrates that existing home dialysis training and support services are limited to a small number of locations.

- The applicant adequately demonstrates that the proposed relocation of the two dialysis stations for HH training and support is needed in addition to the existing or approved dialysis stations for HH and PD training and support.

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.

(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 H, page 49, the applicant provides information about current and projected staffing for the proposed services, as illustrated in the following table.

INS Charlotte Current and Projected Staffing			
	Current	**To Be Added**	**Projected – CY 2021**
Home Training Nurse	2.00	1.00	3.00
Patient Care Technician	0.50	0.00	0.50
Dietitian	0.25	0.08	0.33
Social Worker	0.25	0.08	0.33
Clinical Manager	1.00	0.00	1.00
Administrator	0.15	0.00	0.15
In-service	0.15	0.00	0.15
Clerical	0.50	0.00	0.50
Equipment Technician	0.15	0.00	0.15
Total	**4.95**	**1.16**	**6.11**

Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form A, which is found in Section R. In Section H, page 50, the applicant describes the methods it uses to recruit or fill new positions and its existing training and continuing education programs. In Section I, page 56, the applicant identifies the current medical director. In Exhibit I-5, 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 54, 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 Charlotte – Ancillary and Support Services	
Services	**Provider**
In-center dialysis/maintenance	BMA facility closest to patient residence
Self-care training (in-center)	On site
Home training HH PD Accessible follow-up program	 On site (currently at FMC Charlotte) On site On site
Psychological counseling	Cardinal Innovations; Blue Moon Counseling
Isolation – hepatitis	NA*
Nutritional counseling	On site
Social Work services	On site
Acute dialysis in an acute care setting	Carolinas Medical Center
Emergency care	Crash cart on site/staff trained; ambulance transport to hospital
Blood bank services	Carolinas Medical Center
Diagnostic and evaluation services	Carolinas Medical Center
X-ray services	Carolinas Medical Center
Laboratory services	Spectra
Pediatric nephrology	Carolinas Medical Center
Vascular surgery	Surgical Specialists of Charlotte
Transplantation services	Carolinas Medical Center
Vocational rehabilitation & counseling	Vocational Rehabilitation of Mecklenburg County
Transportation	Mecklenburg Transportation Services

*On page 54, the applicant states that all HH training is performed in individual patient rooms with equipment assigned to the patient and is essentially isolation treatment by its nature.

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

In Section I, pages 56-57, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibits I-3, I-5, and I-7.

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.

NA

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

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and 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 69, the applicant provides the historical payor mix during CY 2017 for its existing services, as shown in the table below.

INS Charlotte Historical Payor Mix CY 2017	
Payment Source	**% Total Patients (PD only)**
Medicare	40.51%
Medicaid	5.22%
Commercial Insurance	41.63%
Medicare/Commercial	6.22%
Misc. (including VA)	6.43%
Total	**100.00%**

The applicant states on pages 69-70 that the existing facility does not currently serve HH patients, and provides the historical payor mix during CY 2017 for HH patients it serves at an affiliated facility, as shown in the table below.

FMC Charlotte Historical Payor Mix CY 2017	
Payment Source	**% Total Patients (HH only)**
Self-Pay/Indigent/Charity	2.25%
Medicare	61.63%
Medicaid	2.74%
Commercial Insurance	33.38%
Total	**100.00%**

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant’s service area.

Percent of Population						
County	**% 65+**	**% Female**	**% Racial & Ethnic Minority***	**% Persons in Poverty****	**% < Age 65 with a Disability**	**% < Age 65 without Health Insurance****
Mecklenburg	11%	52%	53%	12%	6%	12%
Statewide	16%	51%	37%	15%	10%	12%

Source: http://www.census.gov/quickfacts/table; Latest Data 7/1/17 as of 7/17/18
*Excludes *"White alone"* who are *"not Hispanic or Latino"*
***"Estimates are not comparable to other geographic levels due to methodology differences that may exist between different data sources. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable…The vintage year (e.g., V2017) refers to the final year of the series (2010 thru 2017). Different vintage years of estimates are not comparable."*

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consisting of North Carolina, South Carolina and Georgia, provides an Annual Report which includes aggregate ESRD patient data from all three states. The 2016 Annual Report does not provide state-specific ESRD patient data, but the aggregate data is likely to be similar to North Carolina's based on the Network's recent annual reports which included state-specific data.

The IPRO SA Network 6 2016 Annual Report (pages 25-26[2]) provides the following prevalence data on dialysis patients by age, race, and gender. As of December 31, 2016, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 66% were other than Caucasian and 45% were female.

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 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;

[2]https://network6.esrd.ipro.org/wp-content/uploads/sites/4/2017/07/NW6-2016-Annual-Report-FINAL.pdf

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 68, 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 69, 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 66, 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 Charlotte Projected Payor Mix CY 2021			
Payment Source	**% Total Patients**	**% HH Patients**	**% PD Patients**
Self-Pay/Indigent/Charity	4.76%	2.25%	1.59%
Medicare	42.86%	61.63%	45.24%
Medicaid	4.76%	2.74%	3.83%
Commercial Insurance	33.33%	33.38%	35.41%
Medicare/Commercial	4.76%	0.00%	6.46%
Misc. (including VA)	9.52%	0.00%	7.46%
Total	**100.00%**	**100.00%**	**100.00%**

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 4.76 percent of total services will be provided to self-pay, indigent, and charity care patients; 47.62 percent to patients who will have some or all of their care paid for by Medicare, and 4.76 percent to Medicaid patients.

On pages 66-67, 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 payor mix is based on the historical payor mix from the existing facility as well as from another facility with the patient population proposed to be served at the completion of this project.

- Projected utilization is reasonable and adequately supported. 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.

(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 68, 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 72, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-1.

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 two dialysis stations, to be used exclusively for HH patient training and support, from BMA Beatties Ford to INS Charlotte.

On page 365, the 2018 SMFP defines the service area for dialysis stations as *"…the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area."* Thus, the service area is Mecklenburg County. Facilities may serve residents of counties not included in their service area.

According to Table C of the July 2018 SDR, there are eight facilities which provide home dialysis training and support in Mecklenburg County. Information on all eight of these facilities, from Table C of the July 2018 SDR, is provided below:

Mecklenburg County Home Dialysis Patients Facilities with Home Dialysis Patients as of December 31, 2017				
Dialysis Facility	**Owner**	**# HH Patients**	**# PD Patients**	**Total # Patients**
INS Charlotte*	Fresenius	0	13	13
INS Huntersville*	Fresenius	0	7	7
FMC Charlotte	Fresenius	23	55	78
FMC Southwest Charlotte	Fresenius	2	8	10
Carolinas Medical Center	CMC	0	5	5
Charlotte East Dialysis	DaVita	20	35	55
DSI Charlotte Latrobe Dialysis	DSI	2	8	10
DSI Glenwater Dialysis	DSI	3	7	10

Source: July 2018 SDR, Table C.
*Standalone facilities offering exclusively home training and support

In Section N, pages 73-74, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality, and access to the proposed services. On page 73, the applicant states:

> *"The applicant does not expect this proposal to have effect on the competitive climate in Mecklenburg County. The applicant does not project to serve dialysis patients currently being served by another provider. …*
>
> *…*
>
> *Fresenius related facilities have done an exceptional job of containing operating costs while continuing to provide outstanding care and treatment to patients. Every effort is made to (a) ensure that the applicant thoroughly plans for the success of a facility prior to the application, and, (b) that once the project is completed, all staff members work toward the clinical and financial success of the facility. This proposal will certainly not adversely affect quality, but rather, enhance the quality of the ESRD patients' lives by offering a convenient venue for dialysis care and treatment, and promoting access to care."*

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and R of the application and any exhibits).
- Quality services will be provided (see Section O of the application and any exhibits).
- Access will be provided to underserved groups (see Section L 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

In Exhibit A-4, 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 114 dialysis facilities located in North Carolina.

In Section O, page 78, 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 114 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 two dialysis stations from BMA Beatties Ford to INS Charlotte for the purpose of expanding a facility exclusively serving HH and PD patients. 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.