REQUIRED STATE AGENCY FINDINGS

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

Decision Date: November 12, 2021
Findings Date: November 12, 2021

Project Analyst: Julie M. Faenza
Co-signer: Micheala Mitchell

Project ID #: F-12136-21
Facility: Fresenius Kidney Care Regal Oaks
FID #: 150024
County: Mecklenburg
Applicant: Bio-Medical Applications of North Carolina, Inc.
Project: Relocate the home training program and no more than two dialysis stations from FMC Charlotte for a total of no more than 19 stations upon project completion

REVIEW CRITERIA

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

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

NA

Bio-Medical Applications of North Carolina, Inc. (hereinafter "BMA" or "the applicant") proposes to relocate the home training and support program from FMC Charlotte and the two dedicated home hemodialysis (HH) training and support stations at FMC Charlotte to Fresenius Kidney Care Regal Oaks (FKC Regal Oaks) for a total of 19 dialysis stations, including any HH stations, upon project completion.

The applicant does not propose to:

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

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

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

(2) Repealed effective July 1, 1987.

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

C

The applicant proposes to relocate FMC Charlotte's home training and support program and its two dedicated HH training and support stations to FKC Regal Oaks for a total of 19 stations, including any dedicated HH training and support stations, upon project completion.

Patient Origin

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

The following tables illustrate current and projected patient origin.

Current Patient Origin – FKC Regal Oaks & FMC Charlotte – CY 2020								
	FKC Regal Oaks IC* Patients		FMC Charlotte					
			IC* Patients		HH** Patients		PD*** Patients	
	#	%**	#	%	#	%	#	%
Mecklenburg	56	94.9%	149	96.13%	1	50.00%	4	100.00%
Gaston	0	0.0%	3	1.94%	0	0.00%	0	0.00%
Union	2	3.4%	1	0.65%	0	0.00%	0	0.00%
Cabarrus	1	1.7%	0	0.00%	0	0.00%	0	0.00%
Georgia	0	0.0%	1	0.65%	0	0.00%	0	0.00%
South Carolina	0	0.0%	0	0.00%	1	50.00%	0	0.00%
Tennessee	0	0.0%	1	0.65%	0	0.00%	0	0.00%
Total	**59**	**100.0%**	**155**	**100.00%**	**2**	**100.00%**	**4**	**100.00%**

*IC = In-center
**HH = Home hemodialysis
***PD = Home Peritoneal dialysis
Note: Table may not foot due to rounding.
Source: Section C, pages 23-24; Supplemental information requested by the Agency

Projected Patient Origin – FKC Regal Oaks – FY 2 (CY 2024)						
	IC** Patients		HH**** Patients		PD***** Patients	
	#	%***	#	%	#	%
Mecklenburg	59.2	95.1%	11.5	92.0%	10.7	100.0%
Cabarrus	1	1.7%	0	0.0%	0	0.0%
Union	2	3.2%	1	8.0%	0	0.0%
Total	**62.2**	**100.0%**	**12.5**	**100.0%**	**10.7**	**100.0%**

*IC = In-center
**HH = Home hemodialysis
***PD = Home Peritoneal dialysis
Note: Table may not foot due to rounding.
Source: Section C, page 24; Supplemental information requested by the Agency

In Section C, pages 24-30, and immediately following Form C in Section Q, the applicant provides the assumptions and methodology used to project patient origin. The applicant's assumptions are reasonable and adequately supported based on the following:

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

- The applicant does not project any growth in patients residing outside of Mecklenburg County.

- The applicant clearly explains why it expects the home training and support populations to increase.

Analysis of Need

In Section C, pages 24-30 and 32-33, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below.

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

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

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

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

- The current facility is required to move due to plans for development of a new medical school on the land where the current facility is located. The proposed location for the in-center (IC) stations relocating from FMC Charlotte does not have sufficient space to include the home training and support program.

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

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

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

- The applicant includes information from a press release announcing the location and development of the medical school on the land where FMC Charlotte is currently located.

Projected Utilization

In Section C, pages 23-25, 28-30, on Form C in Section Q, and in supplemental information requested by the Agency, the applicant provides historical and projected utilization, as shown in the tables below.

Historical Utilization – FKC Regal Oaks & FMC Charlotte – CY 2020								
	FKC Regal Oaks IC Patients		FMC Charlotte					
			IC Patients		HH Patients		PD Patients	
	#	%**	#	%	#	%	#	%
Mecklenburg	56	94.9%	149	96.13%	1	50.00%	4	100.00%
Gaston	0	0.0%	3	1.94%	0	0.00%	0	0.00%
Union	2	3.4%	1	0.65%	0	0.00%	0	0.00%
Cabarrus	1	1.7%	0	0.00%	0	0.00%	0	0.00%
Georgia	0	0.0%	1	0.65%	0	0.00%	0	0.00%
South Carolina	0	0.0%	0	0.00%	1	50.00%	0	0.00%
Tennessee	0	0.0%	1	0.65%	0	0.00%	0	0.00%
Total	**59**	**100.0%**	**155**	**100.00%**	**2**	**100.00%**	**4**	**100.00%**

Note: Table may not foot due to rounding.

Projected Utilization – FKC Regal Oaks – FY 2 (CY 2024)						
	IC Patients		HH Patients		PD Patients	
	#	%	#	%	#	%
Mecklenburg	59.2	95.1%	11.5	92.0%	10.7	100.0%
Cabarrus	1	1.7%	0	0.0%	0	0.0%
Union	2	3.2%	1	8.0%	0	0.0%
Total	**62.2**	**100.0%**	**12.5**	**100.0%**	**10.7**	**100.0%**

Note: Table may not foot due to rounding.

In Section C, pages 24-30, immediately following Form C in Section Q, and in supplemental information requested by the Agency, the applicant provides the assumptions and methodology used to project patient utilization, which are summarized below.

In-Center

- The applicant begins its utilization projections with the in-center patient census at FKC Regal Oaks on December 31, 2020. The applicant states that on December 31, 2020, it was serving 56 Mecklenburg County patients, two Union County patients, and one Cabarrus County patient.

- The applicant assumes the Mecklenburg County patients will grow at a rate of 3.1 percent per year, which is the 5-year Average Annual Change Rate (AACR) for Mecklenburg County as published in the 2021 SMFP.

- The applicant assumes no population growth for the patients residing in Union and Cabarrus counties but assumes the patients will continue to dialyze at FKC Regal Oaks and adds them to the calculations when appropriate.

- The applicant assumes that, once the project is complete, two in-center patients dialyzing at FKC Regal Oaks will shift to home dialysis each year, with one patient shifting to HH and one patient shifting to PD. The applicant assumes both patients will be Mecklenburg County patients.

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

In Section C, page 25, and immediately following Form C in Section Q, the applicant provides the calculations used to project the in-center patient census for OY1 and OY2, as summarized in the table below.

FKC Regal Oaks In-Center Projected Utilization	
Starting point of calculations is Mecklenburg County in-center patients dialyzing at FKC Regal Oaks on December 31, 2020.	56
Mecklenburg County patient population is projected forward by one year to December 31, 2021, using the Mecklenburg County 5-year AACR (3.1%).	56 X 1.031 = 57.7
Mecklenburg County patient population is projected forward by one year to December 31, 2022, using the Mecklenburg County 5-year AACR (3.1%).	57.7 X 1.031 = 59.5
The patients from Union and Cabarrus counties are added. This is the projected census on December 31, 2022 and the starting census for this project.	59.5 + 3 = 62.5
Mecklenburg County patient population is projected forward by one year to December 31, 2023, using the Mecklenburg County 5-year AACR (3.1%).	59.5 X 1.031 = 61.4
Two Mecklenburg County patients shifting to home dialysis modalities are subtracted.	61.4 – 2 = 59.4
The patients from Union and Cabarrus counties are added. This is the projected census on December 31, 2023 (OY1).	59.4 + 3 = 62.4
Mecklenburg County patient population is projected forward by one year to December 31, 2024, using the Mecklenburg County 5-year AACR (3.1%).	59.4 X 1.031 = 61. 2
Two Mecklenburg County patients shifting to home dialysis modalities are subtracted.	61.2 – 2 = 59.2
The patients from Union and Cabarrus counties are added. This is the projected census on December 31, 2024 (OY2).	59.2 + 3 = 62.2

The applicant projects to serve 62.4 patients on 19 stations, which is 3.3 patients per station per week (62.4 patients / 19 stations = 3.28, which is rounded to 3.3), by the end of OY1 and 62.2 patients on 19 stations, which is 3.3 patients per station per week (62.2 patients / 19 stations = 3.27, which is rounded to 3.3), by the end of OY2. This meets the minimum of 2.8 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

The Project Analyst notes that there is no subpart of 10A NCAC 14C .2203 which is directly applicable to a proposal to increase the number of dedicated HH training and support stations at an existing dialysis facility. In Section C, page 37, the applicant states that the Agency has historically included the number of HH training and support stations located at an in-center dialysis facility in the total number of dialysis stations, because HH training and support stations can also be used to serve in-center patients. When that historical practice is followed in the current application, the applicant does meet the minimum requirements of 10A NCAC 14C .2203(b).

HH and PD Training

- The applicant begins its utilization projections with the HH and PD patient census at FMC Charlotte on December 31, 2020. The applicant states that on December 31, 2020, it was serving one Mecklenburg County HH patient, one HH patient from South Carolina, and four PD patients from Mecklenburg County.

- The applicant assumes the Mecklenburg County patients will grow at a rate of 3.1 percent per year, which is the 5-year Average Annual Change Rate (AACR) for Mecklenburg County as published in the 2021 SMFP.

- The applicant assumes no population growth for the HH patient residing in South Carolina but assumes the patient will continue to be supported by the home training and support program and adds them to the calculations when appropriate.

- The applicant assumes that, once the project is complete, two in-center patients dialyzing at FKC Regal Oaks will shift to home dialysis each year, with one patient shifting to HH and one patient shifting to PD. The applicant assumes both patients will be Mecklenburg County patients.

- The applicant also assumes that three patients dialyzing at FMC Charlotte will shift to home dialysis each year, with two patients shifting to HH and one patient shifting to PD. The applicant projects all three patients will be Mecklenburg County patients.

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

In Section C, page 30, immediately following Form C in Section Q, and in supplemental information requested by the Agency, the applicant provides the calculations used to project the HH and PD patient census for OY1 and OY2, as summarized in the tables below.

FKC Regal Oaks HH Projected Utilization	
Starting point of calculations is Mecklenburg County HH patients dialyzing or receiving support at FKC Charlotte on December 31, 2020.	1
Mecklenburg County patient population is projected forward by one year to December 31, 2021, using the Mecklenburg County 5-year AACR (3.1%).	1 X 1.031 = 1.0
Two Mecklenburg County patients shifting from in-center dialysis to HH are added.	1.0 + 2 = 3.0
Mecklenburg County patient population is projected forward by one year to December 31, 2022, using the Mecklenburg County 5-year AACR (3.1%).	3.0 X 1.031 = 3.1
Two Mecklenburg County patients shifting from in-center dialysis to HH are added.	3.1 + 2 = 5.1
The patient from South Carolina is added. This is the projected census on December 31, 2022 and the starting census for this project.	5.1 + 1 = 6.1
Mecklenburg County patient population is projected forward by one year to December 31, 2023, using the Mecklenburg County 5-year AACR (3.1%).	5.1 X 1.031 = 5.3
Three Mecklenburg County patients shifting from in-center dialysis to HH are added.	5.3 + 3 = 8.3
The patient from South Carolina is added. This is the projected census on December 31, 2023 (OY1).	8.3 + 1 = 9.3
Mecklenburg County patient population is projected forward by one year to December 31, 2024, using the Mecklenburg County 5-year AACR (3.1%).	8.3 X 1.031 = 8.5
Three Mecklenburg County patients shifting from in-center dialysis to HH are added.	8.5 + 3 = 11.5
The patient from South Carolina is added. This is the projected census on December 31, 2024 (OY2).	11.5 + 1 = 12.5

FKC Regal Oaks PD Projected Utilization	
Starting point of calculations is Mecklenburg County PD patients dialyzing or receiving support at FKC Charlotte on December 31, 2020.	4
Mecklenburg County patient population is projected forward by one year to December 31, 2021, using the Mecklenburg County 5-year AACR (3.1%).	4 X 1.031 = 4.1
One Mecklenburg County patient shifting from in-center dialysis to PD is added.	4.1 + 1 = 5.1
Mecklenburg County patient population is projected forward by one year to December 31, 2022, using the Mecklenburg County 5-year AACR (3.1%).	5.1 X 1.031 = 5.3
One Mecklenburg County patient shifting from in-center dialysis to PD is added. This is the projected census on December 31, 2022 and the starting census for this project.	5.3 + 1 = 6.3
Mecklenburg County patient population is projected forward by one year to December 31, 2023, using the Mecklenburg County 5-year AACR (3.1%).	6.3 X 1.031 = 6.5
Two Mecklenburg County patients shifting from in-center dialysis to PD are added. This is the projected census on December 31, 2023 (OY1).	6.5 + 2 = 8.5
Mecklenburg County patient population is projected forward by one year to December 31, 2024, using the Mecklenburg County 5-year AACR (3.1%).	8.5 X 1.031 = 8.7
Two Mecklenburg County patients shifting from in-center dialysis to PD are added. This is the projected census on December 31, 2024 (OY2).	8.7 + 2 = 10.7

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

- The applicant projects future utilization based on historical utilization.
- The applicant projects growth in the Mecklenburg County patient population using the Mecklenburg County 5-year AACR as published in the 2021 SMFP.
- The applicant projects no growth for patients residing outside of Mecklenburg County.
- The applicant adequately supports the projected shifts from in-center dialysis to HH or PD.

Access to Medically Underserved Groups

In Section C, pages 35-36, the applicant states:

> *"…. Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women,* [people with disabilities]*, elderly, or other traditionally underserved persons.*
>
> *It is corporate policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, or health insurer.*
>
> *Fresenius Medical Care and its related facilities in North Carolina have historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender,* [disability]*, age or any other grouping/category or basis for being an underserved person."*

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

Medically Underserved Groups	Estimated % of Total Patients in FY 2
Low income persons	53.6%
Racial and ethnic minorities	85.7%
Women	42.9%
Persons with disabilities	20.2%
Persons 65 and older	34.5%
Medicare beneficiaries	57.1%
Medicaid recipients	29.8%

Source: Section C, page 36

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

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

- The applicant projects the estimates of underserved groups based on the combined experience of FKC Regal Oaks in-center patients and the FMC Charlotte home training and support programs.

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 all the reasons described above.

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

C

The applicant proposes to relocate FMC Charlotte's home training and support program and its two dedicated HH training and support stations to FKC Regal Oaks for a total of 19 stations, including any dedicated HH training and support stations, upon project completion.

In Section D, pages 40-42, the applicant explains why it believes the needs of the population presently utilizing the services to be relocated will be adequately met following completion of the project. The applicant states that the majority of home dialysis patients in Mecklenburg County are served at either INS Charlotte or INS Huntersville, but that a small number of patients have insurance that does not participate with the INS facilities. The applicant states these patients would face higher costs if forced to go to INS facilities for home training and support and support and therefore it needs to maintain a small home training and support program outside of those facilities.

The applicant further states it has no other option except to relocate the home training and support program and that it does not anticipate any difficulties with patients accessing home training and support and support at the new location.

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

- The applicant still plans to serve all patients it previously served.

- The applicant must relocate the facility and does not have another option to keep the services in their existing location.

Access to Medically Underserved Groups

In Section D, page 41, the applicant states that the relocation of the home training and support program from FMC Charlotte to FKC Regal Oaks will not have any effect on the ability of any members of underserved groups to receive home dialysis training and support at FKC Regal Oaks. The applicant further states it is forced to relocate the in-center stations at FMC Charlotte as well, so there will be no remaining patients receiving care at the current location of FMC Charlotte.

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

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

- On page 41, the applicant states it does not project any significant change in the percentages of groups that are potentially underserved through the second full fiscal year following project completion.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

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

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

CA

The applicant proposes to relocate FMC Charlotte's home training and support program and its two dedicated HH training and support stations to FKC Regal Oaks for a total of 19 stations, including any dedicated HH training and support stations, upon project completion.

In Section E, pages 46-47, the applicant states there were no other alternatives to the proposed project. The applicant states that the current location of FMC Charlotte will become part of a large new medical school and the home training and support program from FMC Charlotte has no choice but to vacate the existing location.

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

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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. **Bio-Medical Applications of North Carolina, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application and any supplemental responses. If representations conflict, the certificate holder shall materially comply with the last made representation.**

2. **The certificate holder shall relocate the home training and support program at FMC Charlotte, along with the two dedicated home hemodialysis training stations at FMC Charlotte, to Fresenius Kidney Care Regal Oaks.**

3. **Fresenius Kidney Care Regal Oaks shall be certified for no more than 19 stations, including any home hemodialysis training stations, upon project completion.**

4. **Upon completion of this project, Fresenius Medical Care Holdings, Inc. shall take the necessary steps to decertify two home hemodialysis training stations at FMC Charlotte for a total of no more than 43 in-center stations and no home hemodialysis training stations upon project completion.**

5. **Progress Reports:**

   a. **Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: https://info.ncdhhs.gov/dhsr/coneed/progressreport.html.**

   b. **The certificate holder shall complete all sections of the Progress Report form.**

   c. **The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**

   d. **Progress reports shall be due on the first day of every third month. The first progress report shall be due on March 1, 2022. The second progress report shall be due on June 1, 2022 and so forth.**

6. **The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**

(5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to relocate FMC Charlotte's home training and support program and its two dedicated HH training and support stations to FKC Regal Oaks for a total of 19 stations, including any dedicated HH training and support stations, upon project completion.

Capital and Working Capital Costs

On Form F.1a in Section Q and in supplemental information requested by the Agency, the applicant projects a total capital cost of $18,750 to be used for non-medical equipment and furniture. On Form F.1a, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant describes each item that makes up the projected capital cost.

- The applicant provided the individual and combined cost of each item that makes up the projected capital cost.

In Section F, page 50, the applicant states there are no projected working capital costs because it is an existing facility that is already operational.

Availability of Funds

In Section F, page 48, the applicant states it will fund the capital cost of the proposed project with accumulated reserves. Exhibit F-2 contains a letter from the applicant on behalf of the Senior Vice President and Treasurer of Fresenius Medical Care Holdings, Inc., the parent company of the applicant, authorizing the use of accumulated reserves for the capital needs of the project. The letter in Exhibit F-2 also states that the 2020 Consolidated Balance Sheet for Fresenius Medical Care Holdings, Inc. shows more than $446 million in cash and total assets in excess of $25 billion.

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

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

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

Financial Feasibility

The applicant provides pro forma financial statements for the first two full fiscal years of operation following completion of the project. In supplemental information requested by the Agency, the applicant projects that revenues will exceed operating expenses in the first two full fiscal years following completion of the project, as shown in the table below.

Projected Revenues and Operating Expenses		
FKC Regal Oaks	**FY 1 (CY 2023)**	**FY 2 (CY 2024)**
Total Treatments	11,479	12,267
Total Gross Revenues (Charges)	$72,217,444	$77,169,051
Total Net Revenue	$4,246,508	$4,683,028
Average Net Revenue per Treatment	$370	$382
Total Operating Expenses (Costs)	$3,553,321	$3,783,377
Average Operating Expense per Treatment	$310	$308
Net Income/Profit	**$693,187**	**$899,651**

The assumptions used by the applicant in preparation of the pro forma financial statements are provided immediately following Form F.2, in Forms F.3 and F.4 in Section Q, and in supplemental information requested by the Agency. The applicant adequately demonstrates

that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested 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 demonstrates that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.

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

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

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

C

The applicant proposes to relocate FMC Charlotte's home training and support program and its two dedicated HH training and support stations to FKC Regal Oaks for a total of 19 stations, including any dedicated HH training and support stations, upon project completion.

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

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

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

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

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

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

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

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

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

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

In Section G, page 56, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved dialysis services in Mecklenburg County. The applicant states:

> *"The applicant is not proposing to develop new dialysis stations by this proposal. The applicant proposes to relocate the home therapies program and two existing certified dialysis stations within Mecklenburg County. These stations have been previously approved and do not duplicate services."*

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

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

- The applicant adequately demonstrates that the proposed relocation of the home dialysis training and support program is needed in addition to the existing or approved dialysis services in Mecklenburg County.

Conclusion

The Agency reviewed the:

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

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

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

C

The applicant proposes to relocate FMC Charlotte's home training and support program and its two dedicated HH training and support stations to FKC Regal Oaks for a total of 19 stations, including any dedicated HH training and support stations, upon project completion.

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

FKC Regal Oaks Current and Projected Staffing			
	Current	Projected	
	7/15/2021	CY 2023	CY 2024
Administrator	1.00	1.00	1.00
Registered Nurse	2.50	3.00	3.00
Home Training Nurse	0.00	2.00	3.00
Patient Care Technicians	6.50	7.00	7.00
Dietician	0.67	0.92	0.92
Social Worker	0.67	0.92	0.92
Maintenance	0.50	0.50	0.50
Admin/Business Office	1.00	1.00	1.00
Director of Operations	0.15	0.15	0.15
Chief Technician	0.15	0.15	0.15
FMC In-service	0.15	0.15	0.15
TOTAL	**13.29**	**16.79**	**17.79**

The assumptions and methodology used to project staffing are provided immediately following Form H in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.4 in Section Q. In Section H, pages 58-59, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

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

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to relocate FMC Charlotte's home training and support program and its two dedicated HH training and support stations to FKC Regal Oaks for a total of 19 stations, including any dedicated HH training and support stations, upon project completion.

Ancillary and Support Services

In Section I, page 60, the applicant identifies the necessary ancillary and support services for the proposed services. In Section I, pages 60-65, the applicant explains how each ancillary and support service is or will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

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

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

Coordination

In Section I, page 65, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit H-4. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The facility is an existing facility that has existing relationships with local health care and social service providers.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

(10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

(i) would be available under a contract of at least 5 years duration;
(ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
(iii) would cost no more than if the services were provided by the HMO; and
(iv) would be available in a manner which is administratively feasible to the HMO.

NA

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

(11) Repealed effective July 1, 1987.

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

NA

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

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and … persons [with disabilities], which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs

identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

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

C

In Section L, page 73, the applicant provides the historical payor mix during CY 2020 for its existing services, as shown in the tables below.

FKC Regal Oaks Historical Payor Mix CY 2020 (In-Center)		
Payment Source	**# Patients**	**% Patients**
Self-Pay	3.3	5.57%
Insurance*	8.0	13.54%
Medicare*	36.5	61.93%
Medicaid*	6.7	11.32%
Misc. (including VA)	4.5	7.64%
Total	**59.0**	**100.0%**

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

FMC Charlotte Historical Payor Mix CY 2020						
	IC		**HH**		**PD**	
Payment Source	**# Patients**	**% Patients**	**# Patients**	**% Patients**	**# Patients**	**% Patients**
Self-Pay	8.3	5.36%	0.0	0.00%	0.2	4.76%
Insurance*	19.2	12.38%	1.1	57.41%	1.5	38.38%
Medicare*	111.2	71.77%	0.5	25.98%	2.1	52.74%
Medicaid*	13.9	8.94%	0.1	4.86%	0.2	4.11%
Misc. (including VA)	2.4	1.55%	0.2	11.74%	0.0	0.00%
Total	**155.0**	**100.00%**	**2.0**	**100.00%**	**4.0**	**100.00%**

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

In supplemental information requested by the Agency, the applicant provides the following comparison.

	% of Total Patients Served by FKC Regal Oaks during CY 2020	% of Total Patients Served by FMC Charlotte during CY 2020	% of the Population of Mecklenburg County
Female	42.9%	41.8%	51.9%
Male	57.1%	58.2%	48.1%
Unknown	0.0%	0.0%	0.0%
64 and Younger	65.5%	70.6%	88.5%
65 and Older	34.5%	29.4%	11.5%
American Indian	0.0%	0.0%	0.8%
Asian	3.6%	4.1%	6.3%
Black or African-American	65.5%	72.9%	33.0%
Native Hawaiian or Pacific Islander	2.4%	0.0%	0.1%
White or Caucasian	27.4%	22.9%	46.1%
Other Race	1.2%	0.0%	13.7%
Declined / Unavailable	0.0%	0.0%	0.0%

Sources: BMA Internal Data, US Census Bureau

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested 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 … persons [with disabilities] to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 75, the applicant states it has no such obligation.

In Section L, page 75, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against FKC Regal Oaks.

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 76, and in supplemental information requested by the Agency, 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.

FKC Regal Oaks Projected Payor Mix CY 2024						
	IC		HH		PD	
Payment Source	**# Patients**	**% Patients**	**# Patients**	**% Patients**	**# Patients**	**% Patients**
Self-Pay	3.5	5.57%	0.0	0.00%	0.5	4.76%
Insurance*	8.4	13.54%	7.2	57.41%	4.1	38.38%
Medicare*	38.5	61.93%	3.3	25.98%	5.7	52.74%
Medicaid*	7.0	11.32%	0.6	4.86%	0.4	4.11%
Misc. (including VA)	4.8	7.64%	1.5	11.74%	0.0	0.00%
Total	**62.2**	**100.00%**	**12.5**	**100.00%**	**10.7**	**100.00%**

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

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 5.57 percent of in-center and 4.76 percent of PD services will be provided to self-pay patients; 61.93 percent of in-center, 25.98 percent of HH services and 52.74 percent of PD services to Medicare patients; and 11.32 percent of in-center, 4.86 percent of HH, and 4.11 percent of PD services to Medicaid patients.

On page 76, 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 based on the following:

- The projected payor mix for in-center patients is based on the historical payor mix of in-center patients at FKC Regal Oaks.

- The projected payor mix for HH and PD patients is based on the historical payor mix of HH and PD patients at FMC Charlotte, where the home training and support program is coming from.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency

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, pages 77-78, the applicant adequately describes the range of means by which patients will have access to the proposed services and provides supporting documentation in Exhibit L-4.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to relocate FMC Charlotte's home training and support program and its two dedicated HH training and support stations to FKC Regal Oaks for a total of 19 stations, including any dedicated HH training and support stations, upon project completion.

In Section M, page 79, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting

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

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

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

C

The applicant proposes to relocate FMC Charlotte's home training and support program and its two dedicated HH training and support stations to FKC Regal Oaks for a total of 19 stations, including any dedicated HH training and support stations, upon project completion.

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

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

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

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

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

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

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

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

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

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

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 80, 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 81, the applicant states:

> *"This is a proposal to relocate the home program and two dialysis stations of FMC Charlotte to FKC Regal Oaks. Approval of this application will ensure continued access to care for the patients; this proposal will ensure continued convenient, affordable access to care for home dialysis patients whose insurance provider is not participating with the INS facilities. This is an immediate and significantly positive impact to the patients of the area."*

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

Regarding the impact of the proposal on quality, in Section N, page 81, the applicant states:

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

See also Section O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 81, the applicant states:

> *"All Fresenius Medical Care related facilities in North Carolina have a history of providing dialysis services to the underserved populations of North Carolina. …. Each of those facilities has a patient population which includes low-income persons, racial and ethnic minorities, women,* [people with disabilities]*, elderly, or other traditionally underserved persons.*
>
> *It is corporate policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, or any other factor that would classify a patient as underserved.*
>
> *Fresenius related facilities in North Carolina have historically provided substantial care and services to all persons in need of dialysis services, regardless of income, racial or ethnic background, gender,* [disability]*, age or any other grouping/category or basis for being an underserved person. Low income and medically underinsured persons will continue to have access to all services provided by Fresenius related facilities."*

See also Sections C, D, and L of the application and any exhibits.

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

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

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

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

Conclusion

The Agency reviewed the:

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

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

(19) Repealed effective July 1, 1987.

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

C

The applicant proposes to relocate FMC Charlotte's home training and support program and its two dedicated HH training and support stations to FKC Regal Oaks for a total of 19 stations, including any dedicated HH training and support stations, upon project completion.

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

In Section O, page 86, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents resulting in an Immediate Jeopardy violation that occurred in any of these facilities. After reviewing and considering information provided by the applicant and publicly available data and considering the quality of care provided at all 126 facilities, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

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

C

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

10 NCAC 14C .2203 PERFORMANCE STANDARDS

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

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

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

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

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

-C- In Section C, page 25, and on Form C in Section Q, the applicant projects that FKC Regal Oaks will serve 62.4 patients on 19 stations, or a rate of 3.3 patients per station per week, as of the end of the first operating year following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

(c) An applicant proposing to establish a new dialysis facility dedicated to home hemodialysis or peritoneal dialysis training shall document the need for the total number of home hemodialysis

stations in the facility based on training six home hemodialysis patients per station per year as of the end of the first full fiscal year of operation following certification of the facility.

-NA- FKC Regal Oaks is an existing facility. Therefore, this Rule is not applicable to this review.

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

-NA- FKC Regal Oaks is not a dialysis facility dedicate to home hemodialysis or peritoneal dialysis training. Therefore, this Rule is not applicable to this review.

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

-C- In Section C, pages 24-30, and immediately following Form C in Section Q, the applicant provides the assumptions and methodology it used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.