

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: December 17, 2021

Findings Date: December 17, 2021

Project Analyst: Gregory F. Yakaboski

Co-Signer: Gloria C. Hale

Project ID #: F-12132-21

Facility: FMC Charlotte

FID #: 955947

County: Mecklenburg

Applicant: Bio-Medical Applications of North Carolina, Inc.

Project: Relocate facility to a new location in Charlotte for a total of no more than 46 stations upon completion of this project and Project ID# F-12136-21 (relocate home training program and 2 dialysis stations)

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 FMC Charlotte facility to a new location in Charlotte. FMC Charlotte currently provides in-center (IC) dialysis, a peritoneal dialysis (PD) program, and a home hemodialysis (HH) program. Upon completion of the proposed project and Project ID#F-12136-21 FMC Charlotte will only provide IC dialysis on 46 in-center stations.

FMC Charlotte currently has 48 in-center stations and a home training program. Two of the 48 in-center stations are dedicated hemodialysis stations. In a separate application filed in the same review cycle as this application, the applicant proposes to relocate the home training

program and the 2 in-center stations dedicated to hemodialysis from FMC Charlotte to a different facility. [See Project ID# F-12136-21, relocate home training program and two dialysis stations from FMC Charlotte to Fresenius Kidney Care Regal Oaks (FKC Regal Oaks)].

Fresenius Medical Care Holdings, Inc. (Fresenius) is the ultimate parent company of BMA.

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 applicable 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 the FMC Charlotte facility to a new location in Charlotte. Upon completion of this project and Project ID# F-12136-21 (relocate the home training program and 2 in-center stations dedicated to home hemodialysis from FMC Charlotte to FKC Regal Oaks) FMC Charlotte will have a new location and provide only in-center dialysis on 46 stations.

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.*” The proposed new location for FMC Charlotte is in Charlotte. 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.

Last Full FY (CY2020): FMC Charlotte Patient Origin						
County/State	IC		HH		PD	
	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients
Mecklenburg	149	96.13%	1	50.00%	4	100.00%
Gaston	3	1.94%	0	0.00%	0	0.00%
Union	1	0.65%	0	0.00%	0	0.00%
Georgia	1	0.65%	0	0.00%	0	0.00%
South Carolina	0	0.00%	1	50.00%	0	0.00%
Tennessee	1	0.65%	0	0.00%	0	0.00%
Total	155	100.00%	2	100.00%	4	100.00%

Source: Table on page 24 of the application.

Note: Table may not foot due to rounding.

Projected: FMC Charlotte Patient Origin (CY2024)						
County/State	IC		HH*		PD*	
	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients
Mecklenburg	164.9	97.6%	0	0.00%	0	0.00%
Gaston	3	1.8%	0	0.00%	0	0.00%
Union	1	0.6%	0	0.00%	0	0.00%
Total	168.9	100.00%	0	100.00%	0	100.00%

Source: Table on page 25 of the application

Note: Table may not foot due to rounding.

*Project ID# F-12136-21 (relocate the home training program and 2 in-center stations dedicated to home hemodialysis from FMC Charlotte to FKC Regal Oaks) was conditionally approved on November 12, 2021.

In Section C, pages 25-26, and immediately following Form C in Section Q, the applicant provides the assumptions and methodology used to project patient origin.

- The applicant begins its utilization projections with the in-center patient census at FMC Charlotte on December 31, 2020. The applicant states that on December 31, 2020, it was serving 149 Mecklenburg County patients, three Gaston County patients, one Union County patient and one patient each residing in Georgia and Tennessee respectively.
- 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 Gaston and Union counties but assumes the patients will continue to dialyze at FMC Charlotte and adds them to the calculations when appropriate.

- The applicant assumes the two patients from Georgia and Tennessee were transient patients and does not project these patients to remain at the FMC Charlotte facility.

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.

Analysis of Need

In Section C, pages 25-26 and 31-35, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below.

- 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.
- FMC Charlotte's in-center patient census was 150 patients as of August 1, 2021. This equates to a utilization rate of 81.5% or 3.26 patients per station per week [150 patients / 46 stations = 3.26; $3.26/4 = 0.815$ or 81.5%].

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

- 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.
- Project ID# F-12136-21 (relocate the home training program and 2 in-center stations dedicated to home hemodialysis from FMC Charlotte to FKC Regal Oaks) was conditionally approved on November 12, 2021. This will reduce the number of in-center dialysis stations at FMC Charlotte from 48 to 46.

Projected Utilization

In Section C, pages 24-26, and on Form C in Section Q, the applicant provides historical and projected utilization, as shown in the tables below.

Last Full FY (CY2020): FMC Charlotte Patient Origin						
County/State	IC		HH		PD	
	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients
Mecklenburg	149	96.13%	1	50.00%	4	100.00%
Gaston	3	1.94%	0	0.00%	0	0.00%
Union	1	0.65%	0	0.00%	0	0.00%
Georgia	1	0.65%	0	0.00%	0	0.00%
South Carolina	0	0.00%	1	50.00%	0	0.00%
Tennessee	1	0.65%	0	0.00%	0	0.00%
Total	155	100.00%	2	100.00%	4	100.00%

Source: Table on page 24 of the application.

Note: Table may not foot due to rounding.

Projected: FMC Charlotte Patient Origin (CY2024)						
County/State	IC		HH*		PD*	
	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients
Mecklenburg	164.9	97.6%	0	0.00%	0	0.00%
Gaston	3	1.8%	0	0.00%	0	0.00%
Union	1	0.6%	0	0.00%	0	0.00%
Total	168.9	100.00%	0	100.00%	0	100.00%

Source: Table on page 25 of the application.

Note: Table may not foot due to rounding.

*Project ID# F-12136-21 (relocate the home training program and 2 in-center stations dedicated to home hemodialysis from FMC Charlotte to FKC Regal Oaks) was conditionally approved on November 12, 2021.

In Section C, pages 25-31, and immediately following Form C in Section Q, the applicant provides the assumptions and methodology used to project patient utilization, which are summarized below.

- The applicant begins its utilization projections with the in-center patient census at FMC Charlotte on December 31, 2020. The applicant states that on December 31, 2020, it was serving 149 Mecklenburg County patients, three Gaston County patients, one Union County patient and one patient each residing in Georgia and Tennessee respectively.
- 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 Gaston and Union counties but assumes the patients will continue to dialyze at FMC Charlotte and adds them to the calculations when appropriate.
- The applicant assumes the two patients from Georgia and Tennessee were transient patients and does not project these patients to remain at the FMC Charlotte facility.

- The applicant assumes that three in-center patients dialyzing at FMC Charlotte will shift to home dialysis each year, with two patients projected to shift to HH and one patient projected to shift to PD. The applicant assumes the three patients will be Mecklenburg County patients.
- The project is scheduled to begin offering services on December 31, 2023. OY1 is CY 2024. OY2 is CY 2025.

In Section C, page 26, 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.

FMC Charlotte In-Center Projected Utilization	
Starting point of calculations is Mecklenburg County in-center patients dialyzing at FMC Charlotte on December 31, 2020.	149
Mecklenburg County patient population is projected forward by one year to December 31, 2021, using the Mecklenburg County 5-year AACR (3.1%).	$149 \times 1.031 = 153.6$
Subtract 3 patients shifting from IC dialysis to home dialysis	$153.6 - 3 = 150.6$
Mecklenburg County patient population is projected forward by one year to December 31, 2022, using the Mecklenburg County 5-year AACR (3.1%).	$150.6 \times 1.031 = 155.3$
Subtract 3 patients shifting from IC dialysis to home dialysis	$155.3 - 3 = 152.3$
Mecklenburg County patient population is projected forward by one year to December 31, 2023, using the Mecklenburg County 5-year AACR (3.1%).	$152.3 \times 1.031 = 157.0$
Subtract 3 patients shifting from IC dialysis to home dialysis	$157.0 - 3 = 154.0$
Mecklenburg County patient population is projected forward by one year to December 31, 2024, using the Mecklenburg County 5-year AACR (3.1%).	$154.0 \times 1.031 = 158.8$
Subtract 3 patients shifting from IC dialysis to home dialysis	$158.8 - 3 = 155.8$
Add the 4 patients from Gaston and Union Counties. This is the projected ending patient census for Operating Year 1 (CY2024).	$155.8 + 4 = \mathbf{159.8}$
Mecklenburg County patient population is projected forward by one year to December 31, 2025, using the Mecklenburg County 5-year AACR (3.1%).	$155.8 \times 1.031 = 160.6$
Subtract 3 patients shifting from IC dialysis to home dialysis	$160.6 - 3 = 157.6$
Add the 4 patients from Gaston and Union Counties. This is the projected ending patient census for Operating Year 2 (CY2025).	$157.6 + 4 = \mathbf{161.6}$

The applicant projects to serve 159.8 patients on 46 stations, which is 3.47 patients per station per week ($159.8 \text{ patients} / 46 \text{ stations} = 3.47$). 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).

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.

Access to Medically Underserved Groups

In Section C, page 37, 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	45.1%
Racial and ethnic minorities	86.4%
Women	48.2%
Persons with disabilities	51.8%
Persons 65 and older	53.7%
Medicare beneficiaries	76.3%
Medicaid recipients	45.1%

Source: Section C, page 37.

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 recent facility experience of FMC Charlotte.

Conclusion

The Agency reviewed the:

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

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

- (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 the FMC Charlotte facility to a new location in Charlotte. Upon completion of this project and Project ID# F-12136-21 (relocate the home training program and 2 in-center stations dedicated to home hemodialysis from FMC Charlotte to FKC Regal Oaks) FMC Charlotte will have a new location and provide only in-center dialysis on 46 stations.

In Section D, pages 42-45, 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.

“BMA is proposing to relocate the entire compliment of in-center dialysis stations (46 stations) to the new location. The home dialysis program and two dialysis stations dedicated to home hemodialysis are to be relocated to the FKC Regal Oaks facility. Thus all of the dialysis patients of the facility will continue to have appropriate access to dialysis care.”

The applicant further states it has no other option except to relocate the facility and that it does not anticipate any difficulties for patients to obtain the services 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 43, the applicant states that the relocation of the in-center stations will not have any effect on the ability of any members of underserved groups to receive dialysis at FMC Charlotte. 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 needing in-center dialysis services 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 43, 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.

The applicant proposes to relocate the FMC Charlotte facility to a new location in Charlotte. Upon completion of this project and Project ID# F-12136-21 (relocate the home training program and 2 in-center stations dedicated to home hemodialysis from FMC Charlotte to FKC Regal Oaks) FMC Charlotte will have a new location and provide only in-center dialysis on 46 stations.

In Section E, pages 47-48, the applicant states there were no other alternatives to the proposed project. The applicant states that the property currently occupied by FMC Charlotte is being redeveloped and will become part of a large new medical school and the facility, FMC Charlotte, must vacate from its 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
- 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.**
- 2. The certificate holder shall relocate the existing FMC Charlotte facility to a new location.**
- 3. FMC Charlotte shall be certified for no more than 46 in-center stations upon completion of this project and Project ID# F-12136-21 (relocate the home training program and 2 in-center stations dedicated to home hemodialysis from FMC Charlotte to FKC Regal Oaks).**
- 4. The certificate holder shall install plumbing and electrical wiring through the walls for no more than 46 in- center stations.**

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 the FMC Charlotte facility to a new location in Charlotte. Upon completion of this project and Project ID# F-12136-21 (relocate the home training program and 2 in-center stations dedicated to home hemodialysis from FMC Charlotte to FKC Regal Oaks) FMC Charlotte will have a new location and provide only in-center dialysis on 46 stations.

Capital and Working Capital Costs

In Section Q Form F.1a Capital Cost, page 100, the applicant projects the total capital cost of the project, as summarized below.

Site Costs	\$0
Construction Costs	\$2,402,772
Furniture /Fixtures Costs	\$1,289,023
Total	\$3,691,795

In Section Q, page 100, 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 Sections F.3, page 51, the applicant states there will be no working capital costs (start-up or initial operating expenses) associated with the proposed project since this is an existing facility that is already operational.

Availability of Funds

In Section F.1, page 49, 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 provided pro forma financial statements for the first two full fiscal years of operation following completion of the project. In Form F.2, the applicant projects that revenues will exceed operating expenses in the first two full fiscal years following completion of the project, as shown in the table below.

Projected Revenues and Operating Expenses		
FMC Charlotte	FY 1 (CY 2024)	FY 2 (CY 2025)
Total Treatments	23,517	23,783
Total Gross Revenues (Charges)	\$147,943,227	\$149,620,811
Total Net Revenue	\$7,504,529	\$7,589,626
Average Net Revenue per Treatment	\$319	\$319
Total Operating Expenses (Costs)	\$6,889,666	\$6,995,932
Average Operating Expense per Treatment	\$293	\$294
Net Income/Profit	\$614,864	\$593,694

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. 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

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.

The applicant proposes to relocate the FMC Charlotte facility to a new location in Charlotte. Upon completion of this project and Project ID# F-12136-21 (relocate the home training program and 2 in-center stations dedicated to home hemodialysis from FMC Charlotte to FKC Regal Oaks) FMC Charlotte will have a new location and provide only in-center dialysis on 46 stations.

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.*” The proposed new location for FMC Charlotte is in Charlotte. 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 57, 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 existing certified dialysis stations within Mecklenburg. 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 existing certified dialysis stations 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 the FMC Charlotte facility to a new location in Charlotte. Upon completion of this project and Project ID# F-12136-21 (relocate the home training program and 2 in-center stations dedicated to home hemodialysis from FMC Charlotte to FKC Regal Oaks) FMC Charlotte will have a new location and provide only in-center dialysis on 46 stations.

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

FMC Charlotte Current and Projected Staffing			
	Current FTEs	Projected FTEs	
	7/15/2021	CY 2024	CY 2025
Administrator	1.00	1.00	1.00
Registered Nurse	9.00	9.00	9.00
LPNs	1.00	1.00	1.00
Home Training Nurse	6.00	0.00	0.00
Patient Care Technicians	21.00	21.00	21.00
Dietician	1.50	1.50	1.50
Social Worker	1.50	1.50	1.50
Maintenance	2.00	2.00	2.00
Admin/Business Office	2.00	2.00	2.00
Director of Operations	0.20	0.20	0.20
Chief Technician	0.20	0.20	0.20
FMC In-service	1.25	1.25	1.25
TOTAL	46.65	40.65	40.65

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 59-60, 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 the FMC Charlotte facility to a new location in Charlotte. Upon completion of this project and Project ID# F-12136-21 (relocate the home training program and 2 in-center stations dedicated to home hemodialysis from FMC Charlotte to FKC Regal Oaks) FMC Charlotte will have a new location and provide only in-center dialysis on 46 stations.

Ancillary and Support Services

In Section I, page 61, the applicant identifies the necessary ancillary and support services for the proposed services. In Section I, pages 61-66, 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 66, 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.

C

The applicant proposes to relocate the FMC Charlotte facility to a new location in Charlotte. Upon completion of this project and Project ID# F-12136-21 (relocate the home training program and 2 in-center stations dedicated to home hemodialysis from FMC Charlotte to FKC Regal Oaks) FMC Charlotte will have a new location and provide only in-center dialysis on 46 stations.

In Section K, page 69, the applicant states that the project will involve renovating 16,869 square feet of existing space in an existing building to be rented. The proposed floor plan is provided in Exhibit K-2.

On pages 71-72, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site. Supporting documentation is provided in Exhibit K-4. The site appears to be suitable for the proposed services based on the applicant's representations and supporting documentation.

On pages 69-70, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- Renovations can be accomplished much more cost effectively than building a new structure.
- Fresenius Medical Care Real Estate and Construction Services team has extensive experience developing dialysis facilities and controlling capital expenditures.
- Line drawings are provided in Exhibit K-2.

On page 70, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the following:

- The proposed relocation of FMC Charlotte and 46 in-center stations is necessary to ensure continued convenient access to care for the patients in the area. The proposed project is a necessary part of doing business.
- The cost of adding stations is not passed on the patient - the costs are borne by BMA. The applicant states that the proposed project will not increase costs or charges to the public for the proposed services.

On page 70, the applicant provides the applicable energy saving features that are incorporated into Fresenius related dialysis facilities.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and ... 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 74, the applicant provides the historical payor mix during CY 2020 for its existing services, as shown in the tables below.

FMC Charlotte Historical Payor Mix CY 2020						
Payment Source	IC		HH		PD	
	# 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 Section L, page 75, the applicant provides the following comparison.

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

Sources: BMA Internal Data, US Census Bureau.

Note: The data in the column entitled “% of the Population of Mecklenburg County” was incorrect in the application on page 75. The Project Analyst corrected the data based on publicly available data.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant’s service area which is medically underserved. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and persons with disabilities to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 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 FMC Charlotte.

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, 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.

FMC Charlotte Projected Payor Mix CY 2025						
	IC		HH		PD	
Payment Source	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients
Self-Pay	8.6	5.36%	0.0	0.00%	0.0	0.00%
Insurance*	19.8	12.38%	0.0	0.00%	0.0	0.00%
Medicare*	114.7	71.77%	0.0	0.00%	0.0	0.00%
Medicaid*	14.3	8.94%	0.0	0.00%	0.0	0.00%
Misc. (including VA)	2.5	1.55%	0.0	0.00%	0.0	0.00%
Total	159.8	100.00%	0.0	100.00%	0.0	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 5.36 percent of services will be provided to self-pay patients; 71.77 percent of services to Medicare patients; and 8.94 percent of 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 FMC Charlotte.

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, 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 the FMC Charlotte facility to a new location in Charlotte. Upon completion of this project and Project ID# F-12136-21 (relocate the home training program and 2 in-center stations dedicated to home hemodialysis from FMC Charlotte to FKC Regal Oaks) FMC Charlotte will have a new location and provide only in-center dialysis on 46 stations.

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-1. 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 the FMC Charlotte facility to a new location in Charlotte. Upon completion of this project and Project ID# F-12136-21 (relocate the home training program and 2 in-center stations dedicated to home hemodialysis from FMC Charlotte to FKC Regal Oaks) FMC Charlotte will have a new location and provide only in-center dialysis on 46 stations.

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.*” The proposed new location for FMC Charlotte is in

Charlotte. 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 46 in-center dialysis stations of FMC Charlotte to a new location in Charlotte, Mecklenburg County. The applicant is serving a significant number of dialysis patients residing in the area of the facility. Approval of this application will allow the facility to continue serving patients of the area in a convenient setting. As a result, these patients will have a shorter commute to and from dialysis treatment. This is an immediate and significantly positive impact to the patients of the area.”

See also Sections C, F, 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 the FMC Charlotte facility to a new location in Charlotte. Upon completion of this project and Project ID# F-12136-21 (relocate the home training program and 2 in-center stations dedicated to home hemodialysis from FMC Charlotte to FKC Regal Oaks) FMC Charlotte will have a new location and provide only in-center dialysis on 46 stations.

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.

NA

The Criteria and Standards for End Stage Renal Disease Services promulgated in 10A NCAC 14C .2200 are not applicable to this review.