

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: September 27, 2019

Findings Date: September 27, 2019

Project Analyst: Celia C. Inman

Team Leader: Fatimah Wilson

Project ID #: M-11740-19

Facility: Fresenius Kidney Care Rockfish

FID #: 170017

County: Cumberland

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

Project: Relocate no more than 4 stations from FMC Dialysis Services of West Fayetteville pursuant to Policy ESRD-2 for a total of no more than 25 stations upon completion of this project, Project ID# M-11502-18 (change of scope combining Project ID# M-11286-17 and Project ID #M-11344-18 for a 20-staion facility) and Project ID# M-11650-19 (add 1)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

The applicant, Bio-Medical Applications of North Carolina, Inc. (BMA), proposes to relocate no more than 4 stations from FMC Dialysis Services of West Fayetteville (FMC West Fayetteville) to Fresenius Kidney Care Rockfish (FKC Rockfish) pursuant to Policy ESRD-2 for a total of no more than 25 stations upon completion of this project, Project ID# M-11502-18 (change of scope combining Project ID# M-11286-17 and Project ID #M-11344-18 for a 20-station facility), and Project ID# M-11650-19 (add one station for a total of 21 stations).

FKC Rockfish is not an existing, operational facility; this application proposes to increase the number of stations from 21 to 25 upon the opening of the facility in December 2019. The four projects and number of stations associated with the proposed development of the 25-station FKC Rockfish facility are as follows:

- Project ID #M-11286-17 / Develop FKC Rockfish with 10 stations
- Project ID #M-11502-18 / Combine Project ID #M-11286-17 (10 stations) and Project ID #M-11344-17 (10 stations) to develop a 20-station facility at FKC Rockfish
- Project ID #M-11650-19 / Relocate one station to develop a 21-station facility at FKC Rockfish
- Project ID #M-11740-19 / Relocate four stations to develop a 25-station facility at FKC Rockfish

Need Determination

The 2019 State Medical Facilities Plan (SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to Table D in the July 2019 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of six stations in Cumberland County. However, according to the county need methodology on page 373 of the 2019 State Medical Facilities Plan (SMFP),

“If a county’s December 31, 2019 projected station deficit is less than 10 or if the utilization of any dialysis facility in the county is less than 80 percent, the county’s December 31, 2019 station need is zero.”

The deficit is less than 10 stations; therefore, there is no county need determination for additional dialysis stations in Cumberland County. An applicant is eligible to apply for additional stations in its existing facility based on the facility need methodology if the facility’s utilization rate as reported in the latest SDR is at least 3.2 patients per station per week. FKC Rockfish is a proposed new site approved for 21 stations, but not yet developed and therefore has no utilization to report. Therefore, neither of the two need determination methodologies in the 2019 SMFP apply to this proposal.

Policies

There is one policy in the 2019 SMFP that applies to this review: Policy ESRD-2: Relocation of Dialysis Stations.

Policy ESRD-2, on page 25 of the 2019 SMFP states:

“Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties. Certificate of need applicants proposing to relocate dialysis stations to a contiguous county shall:

1. *Demonstrate that the facility losing dialysis stations or moving to a contiguous county is currently serving residents of that contiguous county; and*

2. *Demonstrate that the proposal shall not result in a deficit, or increase an existing deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report; and*
3. *Demonstrate that the proposal shall not result in a surplus, or increase an existing surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent North Carolina Semiannual Dialysis Report.”*

In Section B.5, page 13, the applicant states that this application proposes a relocation of four dialysis stations within Cumberland County; thus, the applicant adequately demonstrates that the application is consistent with *Policy ESRD-2*.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion because the relocation of four dialysis stations within Cumberland County will have no effect on the number of dialysis stations within the county.

- (2) Repealed effective January 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to relocate four dialysis stations from FMC West Fayetteville to FKC Rockfish for a total of 25 dialysis stations at FKC Rockfish and 36 dialysis stations at FMC West Fayetteville upon project completion.

The following tables illustrate the current and projected number of dialysis stations at FKC Rockfish and FMC West Fayetteville, per the July 2019 SDR and pending relocations and additions, including the proposed project.

FKC Rockfish

# of Stations	Description	Project ID #
0	Total # of existing certified stations as reported in the SDR in effect on the day the review will begin	
4	# of stations to be added as part of this project	M-11740-19
0	# of stations to be deleted as part of this project	
10	# of stations previously approved to be added but not yet certified	M-11286-17
10		M-11502-18
1		M-11650-19
0	# of stations previously approved to be deleted but not yet certified	
0	# of stations proposed to be added in an application still under review	
0	# of stations proposed to be deleted in an application still under review	
25	Total # of stations upon completion of all facility projects	

FMC West Fayetteville

# of Stations	Description	Project ID #
40	Total # of existing certified stations as reported in the SDR in effect on the day the review will begin	
0	# of stations to be added as part of this project	
-4	# of stations to be deleted as part of this project	M-11740-19
5	# of stations previously approved to be added but not yet certified	M-11314-17
1		M-11662-19
-5	# of stations previously approved to be deleted but not yet certified	M-11286-17
-1		M-11650-19
0	# of stations proposed to be added in an application still under review	
0	# of stations proposed to be deleted in an application still under review	
36	Total # of stations upon completion of all facility projects	

As outlined in the tables above, the applicant proposes to relocate four existing dialysis stations from FMC West Fayetteville to the approved but not yet developed FKC Rockfish for a total of 25 stations.

Patient Origin

On page 369, the 2019 SMFP defines the service area for dialysis stations as “*the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.*” FKC Rockfish is proposed for development in Cumberland County. Thus, the service area for this application

is Cumberland County. Facilities may serve residents of counties not included in their service area.

FKC Rockfish is not an existing facility; therefore, there is no current or historical patient origin to report. The applicant does not plan to offer home hemodialysis (home hemo) or peritoneal dialysis (PD) at the facility.

In Section C.1, page 16, the applicant provides a table to illustrate projected patient origin for FKC Rockfish in the second full operating year (OY) following completion of the project. The applicant’s table indicates that CY2022 is the second full operating year following completion of the project; however, the applicant’s proposed timetable in Section P, page 68, shows “*Services Offered*” as of December 31, 2019. Thus, the second full operating year following completion of the project will be CY2021, January 1, 2021 to December 31, 2021. The applicant confirmed the dates in supplemental information requested by the Agency in the expedited review of this project. The following table correctly reflects the applicant’s projected patient origin for the second full operating year following completion of the project.

**FKC Rockfish
 Projected Patient Origin
 CY2021**

County	In-Center		Home Hemo		PD	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Cumberland	59.1	67.4%	NA	NA	NA	NA
Hoke	23.6	26.9%	NA	NA	NA	NA
Robeson	5.0	5.7%	NA	NA	NA	NA
Total	87.7	100.0%	NA	NA	NA	NA

Totals may not sum due to rounding

In Section C, pages 16-17, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.4, page 19, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, stating:

“The need that this population has for the proposed services is a function of the individual patient need for dialysis care and treatment. This question specifically addresses the need that the population to be served has for the proposed project. BMA has identified the population to be served as 82.7 in-center dialysis patients dialyzing with the facility as of the end of the first Operating Year of the project.”

In Section C.5, page 20, the applicant states:

“BMA proposes to relocate four dialysis stations from FMC West Fayetteville to FKC Rockfish. This proposal will increase the number of stations at FKC Rockfish from 21 stations, to 25 stations.

At 21 stations, FKC Rockfish could reasonably project to serve up to 84 in-center dialysis patients on traditional shifts. However, the number of dialysis patients residing near the proposed facility has increased. BMA has identified 10 new dialysis patients, who have signed letters of support for this proposal. Each of these patients began dialysis after the original CON application for FKC Rockfish, and therefore could not have been projected to receive their dialysis care at the facility.

The growth rate of the ESRD patient population in the service area is 4.6%. The 10 newly identified patients, who have indicated their desire to transfer their care to the FKC Rockfish facility, would result in the facility utilization rate of 92.56% from the outset. As a consequence, the facility would have capacity for only five additional stations. Growth of the patient population in the area warrants placing additional stations into the facility.

BMA has elected to place another four stations into the new facility. As this population increases, BMA projects to serve 87.8 patients by the end of Operating Year 2; this is a utilization rate of 87%.”

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

- The applicant bases the need for the relocation of the four stations upon newly identified patients expressing an interest to use the facility along with the number of patients already projected to use the facility from previously approved projects.
- The applicant provides letters of support from the 10 newly identified dialysis patients.
- The applicant utilizes the individual 2019 SDR five-year Average Annual Change Rate (AACR) for Cumberland County and Hoke County to project future patient growth for patients from those two counties.

Projected Utilization

In Section C.3, pages 16-18, and Section Q, pages 77-79, the applicant provides the assumptions and methodology used to project in-center patient utilization, as summarized below:

Assumptions

- BMA identifies the number of patients at FKC Rockfish per previously approved projects:

Project ID #	Project Description	Incremental # Stations	Incremental # Patients	Total # Stations	Total # Patients
M-11286-17	Develop FKC Rockfish	10	32	10	32
M-11502-18	Combine FKC Hope Mills (M-11344-17) with FKC Rockfish	10	32	20	64
M-11650-19	Relocate one station to FKC Rockfish	1	4	21	68

Patient origin of the 68 projected patients: Cumberland County - 50
 Hoke County - 13
 Robeson County – 5

- In addition to the proposed patients from previously approved projects, BMA identified 10 new dialysis patients to propose for services at FKC Rockfish (See support letters in Exhibit C-3.3).

Project ID #	Project Description	Incremental # Stations	Incremental # Patients	Total # Stations	Total # Patients
M-11286-17	Develop FKC Rockfish	10	32	10	32
M-11502-18	Combine FKC Hope Mills (M-11344-17) with FKC Rockfish	10	32	20	64
M-11650-19	Relocate one station to FKC Rockfish	1	4	21	68
M-11740-19	Relocate four stations to FKC Rockfish	4	10	25	78

Patient origin of the 78 projected patients: Cumberland County - 54
 Hoke County - 19
 Robeson County – 5

The applicant states that the facility will open with the 68 patients from previously approved projects, with 50 of the 68 patients from Cumberland County and 13 from Hoke County. The additional 10 patients will be added following the opening of the facility, with four patients from Cumberland County and six from Hoke County.

- BMA projects growth of the Cumberland County patient population using the Cumberland County five-year AACR of 4.6% from the July 2019 SDR.

- BMA projects growth of the Hoke County patient population using the Hoke County five-year AACR of 11.5% from the July 2019 SDR.
- Project completion is scheduled for December 31, 2019; OY 1 is CY2020 and OY2 is CY2021.
- Because of the relatively few number of proposed Robeson County patients, BMA projects no growth in the Robeson County patients who will transfer their care to the proposed facility.

Methodology

Begin with 50 Cumberland County patients previously projected from Project ID #s M-11286-17, M-11502-18, and M-11650-19 as of December 31, 2019, projected date of completion.	50
Add 4 new Cumberland County patients projected to transfer care as of December 31, 2019	$50 + 4 = 54$
Begin with 13 Hoke County patients previously projected from Project ID #s M-11286-17, M-11502-18, and M-11650-19 as of December 31, 2019, projected date of completion.	13
Add 6 new Hoke County patients projected to transfer care as of December 31, 2019	$13 + 6 = 19$
Sum the census of the patients from Cumberland, Hoke and Robeson counties for beginning census	$54 + 19 + 5 = 78$
Project Growth of Cumberland County and Hoke County patients using the respective AACR	$54 \times 1.046 = 56.48$ $19 \times 1.115 = 21.19$
Sum the census of the patients from Cumberland, Hoke and Robeson counties for ending census OY1	$56.48 + 21.19 + 5 = 82.67$
Project Growth of Cumberland County and Hoke County patients using the respective AACR	$56.48 \times 1.046 = 59.08$ $21.19 \times 1.115 = 23.62$
Sum the census of the patients from Cumberland, Hoke and Robeson counties for ending census OY2	$59.08 + 23.62 + 5 = 87.7$

The applicant projects to serve 82.67 in-center dialysis patients on 25 stations at the end of OY 1, and 87.7 in-center dialysis patients on 25 stations at the end of OY 2, which is 3.3 patients per station per week at the end of OY 1, or 83% of capacity [$82.7 / 25 = 3.3$; $3.3 / 4 = 0.83$]; and 3.5 patients per station per week at the end of OY 2, or 88% of capacity [$87.7 / 25 = 3.5$; $3.5 / 4 = 0.88$].

Therefore, the applicant’s projected utilization exceeds the minimum of 3.2 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 uses the individual five-year AACRs for Cumberland and Hoke counties, as published in the July 2019 SDR, to project growth of in-center patient utilization.
- The applicant projects growth of the Cumberland and Hoke County patient populations because the majority of the projected patients will come from those counties. The applicant does not project growth for Robeson County patients.
- The applicant’s projects in-center patient utilization exceeds the minimum of 3.2 patients per station per week as of the end of the first operating year as required by 10A NCAC 14C .2203(b).

Access

In Section C.7, pages 21-22, the applicant states:

“BMA, and its parent organization, Fresenius Medical Care Holdings, Inc., has a long history of providing dialysis services to the underserved populations of North Carolina. The Form A within Section Q identifies 127 Fresenius related, North Carolina dialysis facilities which are either operational or CON approved and at some stage of development. . . . Each of our facilities has a patient population which includes low-income persons, racial and ethnic minorities, women, handicapped persons, elderly, or other traditionally underserved persons.

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

In Section L.3, page 57, the applicant projects the following payor mix during the second full year of operation following completion of the project, as summarized in the following table:

**Projected Payor Mix
CY2021**

PAYOR	% OF TOTAL
Self-Pay	0.92%
Insurance*	74.35%
Medicare*	5.20%
Medicaid*	3.80%
Medicare / Commercial	12.08%
Miscellaneous (includes VA)	3.65%
Total	100.00%

Totals may not sum due to rounding

*Including any managed care plans

The above projected payor mix, as provided in the application, appears questionable compared to FMC West Fayetteville’s historical payor mix and other BMA dialysis projects.

In supplemental information requested by the Agency in the expedited review of the project, the applicant confirmed that an error was made in recording the information into the table above. The projected payor mix should have been recorded as follows:

**Projected Payor Mix
CY2021**

PAYOR	# OF PATIENTS[^]	% OF TOTAL
Self-Pay	1	0.92%
Insurance*	3	3.80%
Medicare*	65	74.35%
Medicaid*	8	5.20%
Medicare / Commercial	11	12.08%
Miscellaneous (includes VA)	3	3.65%
Total	88	100.00%

Totals may not sum due to rounding

[^]# of Patients is estimated based upon treatment volume payor mix and does not calculate exactly, as the applicant states on page 56 of the application, "Fresenius reporting does not lend itself to reporting payor mix based solely upon the whole patient."

*Including any managed care plans

The projected payor mix, as stated in the supplemental information requested by the Agency, is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application,
- information publicly available during the review and used by the Agency, and
- 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 identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported. The applicant reasonably projects that the utilization rate of the new facility will be 3.3 patients per station per week at the end of OY 1, which exceeds the required minimum operating standard promulgated in 10A NCAC 14C .2203(b), based on the growth of Cumberland and Hoke County patients at the individual five-year AACRs, as published in the July 2019 SDR.

- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.
- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

C

The applicant proposes to relocate four dialysis stations from FMC West Fayetteville to the approved but not yet developed FKC Rockfish facility, for a total of 36 certified dialysis stations at FMC West Fayetteville and 25 certified dialysis stations at FKC Rockfish upon project completion. Both facilities are in Cumberland County.

In Section D, pages 25-29, the applicant explains why it believes the needs of the population presently dialyzing at FMC West Fayetteville will be adequately met following the relocation of four in-center stations to FKC Rockfish.

On page 25, the applicant states that this proposal will have no effect upon the needs of the patients currently utilizing the stations that will be relocated. The station relocation is scheduled to be completed as of December 31, 2019. BMA has projected that 42 patients would transfer their care from FMC West Fayetteville to FKC Rockfish: 30 from Cumberland County, 10 from Hoke County and two from Robeson County. Thus, after station relocation and patient transfers, the applicant states that the FMC West Fayetteville census is projected to be 131.5 patients dialyzing on 36 stations or 3.65 patients per station. The applicant provides the calculations on page 28.

Per the July 2019 SDR, FMC West Fayetteville is currently serving 177 patients on 40 certified dialysis stations. Based on the facility census as shown above, the facility was operating at 111% of capacity as of December 31, 2018 [$177 \text{ patients} / 40 \text{ stations} = 4.425$; $4.425 / 4 = 1.106$].

On page 25, the applicant states that the Facility Need Methodology, based on the July 2019 SDR data, demonstrates that FMC West Fayetteville qualifies to apply for up to 10 additional stations. The applicant provides its need methodology calculation on page 26; however, the applicant erroneously uses 166 patients (the number of patients for FMC Dialysis Services South Ramsey shown in the row above FMC West Fayetteville) for patients as of 6/30/18, instead of the correct 156 patients, as shown in the January 2019 SDR (SDR1) .

The following table uses the correct number of patients from the January 2019 SDR (SDR1) and calculates the need for additional stations at FMC West Fayetteville.

OCTOBER 1 REVIEW-JULY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 12/31/18		110.63%
Certified Stations		40
Pending Stations		6
Total Existing and Pending Stations		46
In-Center Patients as of 12/31/18 (July 2019 SDR) (SDR2)		177
In-Center Patients as of 6/30/18 (January 2019 SDR) (SDR1)		156
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	21
	Multiply the difference by 2 for the projected net in-center change	42
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 6/30/18	0.2692
(ii)	Divide the result of Step (i) by 12	0.0224
(iii)	Multiply the result of Step (ii) by 12 (the number of months from 12/31/17 until 12/31/18)	0.2692
(iv)	Multiply the result of Step (iii) by the number of in-center patients reported in SDR2 and add the product to the number of in-center patients reported in SDR2	224.6538
(v)	Divide the result of Step (iv) by 3.2 patients per station	70.2043
	and subtract the number of certified and pending stations to determine the number of stations needed	24.2043

As shown in the table above, the applicant will have the opportunity to apply for additional stations in the October 1, 2019 review period. The applicant states intent to apply for four stations in September 2019 for the October 1, 2019 review. Consequently, BMA does not anticipate any adverse effects would be realized by the patient population dialyzing at FMC West Fayetteville. The stations would be replaced virtually immediately upon relocation.

In Section D.3, on page 27, the applicant states that the relocation of stations as proposed in this application will have no effect on the ability of low income persons, racial and ethnic minorities, women, handicapped, elderly and other groups to obtain needed dialysis treatments. BMA proposes to replace the stations at FMC West Fayetteville shortly after completion of the relocation of the stations. Further, the applicant states that the utilization arising from the relocation of stations does not impede admission to the facility.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

- The needs of the population currently using the services to be relocated will be adequately met following project completion.
 - The project will not adversely impact the ability of underserved groups to access these services following project completion.
- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

The applicant proposes to relocate four dialysis stations from FMC West Fayetteville to FKC Rockfish for a total of 25 dialysis stations at FKC Rockfish upon project completion.

In Section E, page 30, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the status quo - The applicant states that maintaining the status quo is not an effective alternative because it fails to recognize the growth of the patient population residing in the area of the FKC Rockfish development and does not ensure an adequate station capacity for the area patients.
- Relocate fewer stations – The applicant states that relocating fewer than four stations does not adequately meet the needs of the growing patient population of the area.

On page 30, the applicant states that after considering the above alternatives, BMA elected to relocate four stations to the new facility because this is a cost-effective approach to provide the necessary services for the projected population to be served by the facility.

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

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provided credible information to explain why it believes the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information which was publicly available during the review and used by the Agency.

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

- 1. Bio-Medical Applications of North Carolina, Inc. shall materially comply with all representations made in the certificate of need application and any supplemental responses. In the event that representations conflict, Bio-Medical Applications of North Carolina, Inc. shall materially comply with the last made representation.**
 - 2. Pursuant to Policy ESRD-2, Bio-Medical Applications of North Carolina, Inc. shall relocate no more than four dialysis stations from FMC Services of West Fayetteville to Fresenius Kidney Care Rockfish for a total of no more than 25 stations upon the completion of this project, Project ID# M-11502-18 (change of scope combining Project ID# M-11286-17 and Project ID #M-11344-18 for a 20-station facility), and Project ID #M-11650-19 (add 1 station).**
 - 3. Bio-Medical Applications of North Carolina, Inc. shall install plumbing and electrical wiring through the walls for no more than four additional dialysis stations which shall include any isolation stations, for a total of no more than 25 stations at Fresenius Kidney Care Rockfish.**
 - 4. Upon completion of this project, Bio-Medical Applications of North Carolina, Inc. shall take the necessary steps to decertify four dialysis stations at FMC Services of West Fayetteville for a total of no more than 36 dialysis stations at FMC Services of West Fayetteville upon completion of this project, Project ID # M-11286-17 (relocate 5 stations), Project ID # M-11314-17 (add 5 stations), Project ID # M-11650-19 (relocate 1 station), and Project ID # M-11662-19 (add 1 station).**
 - 5. Bio-Medical Applications of North Carolina, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section in writing prior to the 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 four dialysis stations from FMC West Fayetteville to FKC Rockfish for a total of 25 dialysis stations at FKC Rockfish.

Capital and Working Capital Costs

In Section Q, Form F.1b Capital Cost, page 85, the applicant projects the total new capital cost of the development of the FKC Rockfish facility and the capital cost of this project, to relocate four stations for a total of 25 stations. The four projects associated with the proposed development of the 25-station FKC Rockfish facility are as follows:

- Project ID #M-11286-17 / Develop FKC Rockfish with 10 stations
- Project ID #M-11502-18 / Combine Project ID #M-11286-17 (10 stations) and Project ID #M-11344-17 (10 stations) to develop a 20-station facility at FKC Rockfish
- Project ID #M-11650-19 / Relocate one stations to develop a 21-station facility at FKC Rockfish
- Project ID #M-11740-19 / Relocate four stations to develop a 25-station facility at FKC Rockfish

The total capital cost of the development of the proposed 25-station FKC Rockfish dialysis facility is as summarized in the table below:

	Project ID #M-11286-17	Project ID #M-11502-18	Project ID #M-11650-19	Project ID #M-11740-19	Difference
	10 Stations	20 Stations	21 Stations	25 Stations	Relocate 4 Stations
	Total Capital Cost to Develop FKC Rockfish	Total Capital Cost to Develop FKC Rockfish	Total Capital Cost to Develop FKC Rockfish	New Total Capital Cost to Develop FKC Rockfish	Capital Cost for the Proposed COS Project
Construction/Renovation	\$1,047,563	\$1,482,788	\$1,482,788	\$1,482,788	\$0
Architect/Engineer Fees	\$94,281	\$133,451	\$133,451	\$133,451	\$0
Non-medical Equipment	\$225,000	\$225,000	\$225,750	\$228,750	\$3,000
Furniture	\$145,077	\$241,011	244011	256011	\$12,000
Contingency	\$57,092	\$80,812	\$80,812	\$80,812	\$0
Total	\$1,569,013	\$2,163,062	\$2,166,812	\$2,181,812	\$15,000

Totals may not sum due to rounding

In Section F.3, pages 33-34, the applicant projects start-up expenses of \$359,680 and initial operating expenses of \$1,512,678 for a total working capital of \$1,872,358. The applicant states that this application assumes a start-up period of four weeks and an initial operating period of six months. The facility has previously been approved for a total working capital of \$1,916,744.

Availability of Funds

In Section F.2, page 32, the applicant states that the \$15,000 capital cost for this project will be funded as shown in the table below.

TYPE	BIO-MEDIAL APPLICATIONS OF NORTH CAROLINA, INC.
Loans	0
Accumulated Reserves or OE*	\$15,000
Other (Specify)	0
Total	\$15,000

*OE = Owner's Equity

Exhibit F-2 contains a letter dated July 15, 2019 from the Senior Vice President and Treasurer of Fresenius Medical Care Holdings, Inc., parent company of BMA, authorizing and committing “cash reserves for the capital cost of \$15,000, and any start-up expenses and initial operating expenses as may be needed” for the project. The letter in Exhibit F-2 also states that Fresenius Medical Care Holdings, Inc.’s 2017 Consolidated Balance Sheet reflects more than \$1.8 billion in cash and total assets exceeding \$20 billion. The development of the FKC Rockfish facility (in previously approved projects) has already demonstrated the availability of adequate working capital for facility development.

Financial Feasibility

The applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Section Q, Form F.2, page 86, the applicant projects that revenues will exceed operating expenses in the second operating year of the project, as shown in the table below.

	OY 1 CY2020	OY 2 CY2021
Total In-Center Treatments	11,150	12,608
Total Gross Revenues (Charges) Form F.3	\$70,141,542	\$79,314,210
Total Net Revenue	\$3,016,709	\$3,411,215
Average Net Revenue per Treatment	\$271	\$271
Total Operating Expenses (Costs) Form F.4	\$3,025,356	\$3,201,207
Average Operating Expense per Treatment	\$271	\$254
Net Income	(\$8,647)	\$210,008

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

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

C

The applicant proposes to relocate four dialysis stations from FMC West Fayetteville to FKC Rockfish for a total of 25 dialysis stations at FKC Rockfish.

On page 369, the 2019 SMFP defines the service area for dialysis stations as *“the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.”* FKC Rockfish is proposed for development in Cumberland County. Thus, the service area is Cumberland County. Facilities may serve residents of counties not included in their service area.

According to the July 2019 SDR, there are five existing or approved dialysis facilities in Cumberland County, all of which are or will be operated by the applicant or a related entity. Information on all of these dialysis facilities, from Table B of the July 2019 SDR, is provided below:

**Cumberland County Dialysis Facilities
 Certified Stations and Utilization as of December 31, 2018**

DIALYSIS FACILITY	LOCATION	# OF CERTIFIED STATIONS	# PATIENTS	UTILIZATION
Fayetteville Kidney Center	Fayetteville	50	169	84.50%
FMC Dialysis Services North Ramsey	Fayetteville	40	155	96.88%
FMC Dialysis Services South Ramsey	Fayetteville	51	147	72.06%
FMC Services of West Fayetteville	Fayetteville	40	177	110.63%
Fresenius Kidney Care Rockfish	Fayetteville	21*	0	0.00%

*Stations are approved but not yet certified.

According to Table D in the July 2019 SDR, there is a deficit of 6 dialysis stations in Cumberland County. The applicant proposes to relocate four dialysis stations within

Cumberland County. In Section G, page 41, the applicant states that its proposal to relocate existing dialysis stations within the county is a redistribution of existing and certified stations and will not result in duplicated services. The applicant states it seeks to improve access to care, making care more convenient for the patients served and to be served.

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

- The proposal relocates four existing dialysis stations from one BMA facility to another in Cumberland County, and therefore would not result in an increase in the number of dialysis stations in Cumberland County.
- The applicant adequately demonstrates that the proposed relocation of dialysis stations is needed in addition to the existing and approved stations in Cumberland County.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- 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.

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

C

In Section Q, Form H, page 94, the applicant projects full-time equivalent (FTE) positions for the proposed services for the first two full operating years, as illustrated in the following table:

POSITION	TOTAL FTE POSITIONS CY2020 AND CY2021
Administrator	1.00
Registered Nurse	3.00
Patient Care Technician	10.00
Dietician	0.90
Social Worker	0.90
Maintenance (Equipment Technician)	0.75
Administration/Business Office	1.00
FMC Director of Operations	0.20
In-Service	0.20
Chief Technician	0.15
Total FTE Positions	18.05

The assumptions and methodology used to project staffing are provided in Section Q, page 95. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.4, which is found in Section Q. In Section H, page 43, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H.4, page 44, the applicant identifies Richmond Nuamah, M. D. as the proposed medical director. In Exhibit H.4, the applicant provides a letter from Mark Kasari, M.D., representing himself as the facility's medical director. In supplemental information requested by the Agency, the applicant confirms that Dr. Kasari, as documented in Exhibit H.4, will serve as the medical director.

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

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- supplement information requested by the Agency.

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

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

In Section I.1, pages 45-46, the applicant includes a list of providers of the necessary ancillary and support services and shows how they will be provided.

FKC ROCKFISH ANCILLARY AND SUPPORT SERVICES	
SERVICES	PROVIDER
In-center dialysis/maintenance	Fayetteville Kidney Center
Self-care training (in-center)	Fayetteville Kidney Center
Home Training HH PD Accessible follow-up program	Fayetteville Kidney Center Fayetteville Kidney Center Fayetteville Kidney Center
Isolation – hepatitis	BMA – on site
Nutritional counseling	BMA – on site
Social Work services	BMA – on site
Laboratory services	BMA – on site Spectra Labs
Vascular surgery	Drs. Ross, Chang, or Husain
Pediatric nephrology	UNC Healthcare
Acute dialysis in an acute care setting	Cape Fear Valley Hospital
Transplantation services	UNC Healthcare
Emergency care	BMA/911
Blood bank services	Cape Fear Valley Hospital
Diagnostic and evaluation services	Cape Fear Valley Radiology
X-ray services	Cape Fear Valley Radiology
Psychological counseling	Cumberland County Mental Health
Vocational rehabilitation & counseling	Cumberland County Vocational Rehabilitation Services
Transportation	Fayetteville Area System Transit, Medlink, Cape Fear Regional Transport, Cumberland County Department of Social Services, Reliable Transportation

In Section I.2, pages 46-47, the applicant describes its existing and proposed relationships with the local health care providers and provides supporting documentation in Exhibits I-1, I-2, I-3 and I-4. In addition, on page 44, the applicant provides a list of nephrologists who have agreed to refer and admit patients at the facility.

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

Conclusion

The Agency reviewed:

- application, and
- exhibits to the application.

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

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

NA

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

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

NA

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

- (11) Repealed effective January 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 associated with the relocation of the four stations as proposed in this application. The full cost of the proposed construction

for the FKC Rockfish facility was accounted for in Project ID# M-11502-18. Therefore, Criterion (12) is not applicable to this review. The discussion on capital cost found in Criterion (5) is incorporated herein by reference.

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

C

FKC Rockfish is not yet developed. In Section L.1(b), page 56, the applicant provides the historical payor mix during CY2018 at FMC West Fayetteville, the facility from which four stations will be relocated, as summarized in the table below.

**Historical Payor Mix
FMC West Fayetteville
CY2018**

PAYOR	% OF TOTAL IN-CENTER PATIENTS
Self-Pay	0.92%
Insurance*	3.80%
Medicare*	74.35%
Medicaid*	5.20%
Medicare / Commercial	12.08%
Miscellaneous (includes VA)	3.65%
Total	100.00%

Totals may not sum due to rounding

*Including any managed care plans

In Section L.1(a), page 55, the applicant provides comparison of the demographical information on FMC West Fayetteville patients and what should be the service area patients during CY2018.

	Percentage of Total Patients Served during the Last Full FY	Percentage of the Population of the Service Area
Female	44.0%	52.3%
Male	56.0%	47.7%
Unknown	Not Available	Not Available
64 and Younger	55.4%	86.9%
65 and Older	44.6%	13.1%
American Indian	1.2%	0.9%
Asian	1.2%	5.5%
Black or African-American	79.5%	37.3%
Native Hawaiian or Pacific Islander	0.6%	0.1%
White or Caucasian	8.4%	53.7%
Other Race	9.0%	2.5%
Declined / Unavailable	Not Available	Not Available

* The percentages can be found online using the United States Census Bureau’s QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>. Just enter in the name of the county.

However, the applicant states on page 55 that the above table includes the demographic data for FMC West Fayetteville and Wake County. In supplemental information requested by the Agency, the applicant provides the following information for FMC West Fayetteville and the service area, Cumberland County.

	Percentage of Total Patients Served during the Last Full FY	Percentage of the Population of the Service Area
Female	44.0%	50.5%
Male	56.0%	49.5%
Unknown	Not Available	Not Available
64 and Younger	55.4%	88.1%
65 and Older	44.6%	11.9%
American Indian	1.2%	1.5%
Asian	1.2%	2.8%
Black or African-American	79.5%	39.0%
Native Hawaiian or Pacific Islander	0.6%	0.4%
White or Caucasian	8.4%	42.6%
Other Race	9.0%	13.4%
Declined / Unavailable	Not Available	Not Available

* The percentages can be found online using the United States Census Bureau’s QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>. Just enter in the name of the county.

The Agency reviewed the:

- application,
- exhibits to the application,
- information publicly available during the review and used by the Agency and
- supplemental information requested by the Agency.

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

The applicant adequately demonstrates that it currently provides access to medically underserved populations. Therefore, the application is conforming to this criterion.

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.2(a), page 56, the applicant states:

“BMA of North Carolina facilities do not have any obligation to provide uncompensated care or community service under any federal regulations. The facility will be responsible to provide care to both minorities and handicapped people. The applicant will treat all patients the same regardless of race or handicap status.”

In Section L.2(c), page 57, the applicant states that no patient civil rights access complaints have been filed against any BMA North Carolina facilities during the past five years.

The Agency reviewed the:

- application,
- exhibits to the application, and
- 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.

- (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.3, page 57, the applicant projects the following payor mix for the proposed services during the second full year of operation following completion of the project, as summarize in the table below.

**Projected Payor Mix
CY2021**

PAYOR	% OF TOTAL
Self-Pay	0.92%
Insurance*	74.35%
Medicare*	5.20%
Medicaid*	3.80%
Medicare / Commercial	12.08%
Miscellaneous (includes VA)	3.65%
Total	100.00%

Totals may not sum due to rounding

*Including any managed care plans

The above projected payor mix, as provided in the application, appears questionable compared to FMC West Fayetteville's CY2018 payor mix and other BMA dialysis projects. In supplemental information requested by the Agency in the expedited review of the project, the applicant confirmed that an error was made in recording the information into the table above. The projected payor mix should have been recorded as follows:

**Projected Payor Mix
CY2021**

PAYOR	% OF TOTAL
Self-Pay	0.92%
Insurance*	3.80%
Medicare*	74.35%
Medicaid*	5.20%
Medicare / Commercial	12.08%
Miscellaneous (includes VA)	3.65%
Total	100.00%

Totals may not sum due to rounding

*Including any managed care plans

As shown in the table above, during the second full year of operation, the applicant projects that 0.92% of total services will be provided to self-pay patients, 86.43% to Medicare patients (including Medicare/commercial) and 5.20% to Medicaid patients.

On page 57, the applicant provides the assumptions and methodology used to project payor mix during the second full year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because the projected payor mix is based on the historical experience of FMC West Fayetteville, the closest BMA facility to the location of FKC Rockfish and from which patients will be transferring to obtain dialysis services at FKC Rockfish.

The Agency reviewed the:

- application,

- exhibits to the application,
- information publicly available during the review and used by the Agency and
- 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.5, page 58, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- application, and
- exhibits to the application.

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

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

C

In Section M, page 60, 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 Agency reviewed the:

- application, and
- exhibits to the application.

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

- (15) Repealed effective January 1, 1987.
(16) Repealed effective January 1, 1987.
(17) Repealed effective January 1, 1987.
(18) Repealed effective January 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 four dialysis stations from FMC West Fayetteville to FKC Rockfish for a total of 25 dialysis stations at FKC Rockfish upon project completion.

On page 369, the 2019 SMFP defines the service area for dialysis stations as *“the planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.”* FKC Rockfish is proposed for development in Cumberland County. Thus, the service area is Cumberland County. Facilities may serve residents of counties not included in their service area.

According to the July 2019 SDR, there are five existing or approved dialysis facilities in Cumberland County, all of which are or will be operated by the applicant or a related entity. Information on all of these dialysis facilities, from Table B of the July 2019 SDR, is provided below:

**Cumberland County Dialysis Facilities
 Certified Stations and Utilization as of December 31, 2018**

DIALYSIS FACILITY	LOCATION	# OF CERTIFIED STATIONS	# PATIENTS	UTILIZATION
Fayetteville Kidney Center	Fayetteville	50	169	84.50%
FMC Dialysis Services North Ramsey	Fayetteville	40	155	96.88%
FMC Dialysis Services South Ramsey	Fayetteville	51	147	72.06%
FMC Services of West Fayetteville	Fayetteville	40	177	110.63%
Fresenius Kidney Care Rockfish	Fayetteville	21*	0	0.00%

*Stations are approved but not yet certified.

According to Table D in the July 2019 SDR, there is a deficit of 6 dialysis stations in Cumberland County. The applicant proposes to relocate four dialysis stations within Cumberland County.

In Section N, pages 61-63, the applicant states that it does not expect the proposed project to have any effect on the competitive climate of Cumberland County, and discusses how the proposal will promote the cost-effectiveness, quality and access to the proposed services. On page 62, the applicant states:

“BMA proposed to add four stations to this facility for a modest expenditure of only \$15,000. This is a most cost effective approach to expanding dialysis service in the county.

...

Fresenius Medical Care, parent organization for this facility, expects every facility to provide high quality care to every patient at every treatment.

...

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

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

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

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- 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.

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

C

In Section O.2, page 67, the applicant states that Section Q, Form A, pages 70-75, identifies all of the Fresenius related facilities across North Carolina. Form A lists 127 Fresenius related dialysis facilities.

In Section O.3(b), page 67, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no quality of care incidents that resulted in a finding of “*Immediate Jeopardy*” (IJ) in any of the Fresenius related facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all Fresenius facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective January 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

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

10 NCAC 14C .2203 PERFORMANCE STANDARDS

- .2203(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least 10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities Plan that is based on an adjusted need determination.*
- NA- The applicant does not propose to establish a new End Stage Renal Disease facility. Therefore, this performance standard is not applicable to this review.
- .2203(b) An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility or one that was not operational prior to the beginning of the review period but which had been issued a certificate of need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the additional stations.*
- C- In Section Q, Form C Utilization, page 76, and in Section C.3(b), page 18, the applicant projects to serve 82.7 in-center patients on 25 in-center stations by the end of OY 1, which is 3.3 patients per station per week [$82.7 / 25 = 3.3$]. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

.2203(c) *An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.*

-C- In Section Q, pages 77-79, the applicant provides the assumptions and methodology used to project utilization of the facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.