

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: July 6, 2017

Findings Date: July 6, 2017

Project Analyst: Tanya S. Rupp

Team Leader: Fatimah Wilson

Project ID #: M-11314-17

Facility: FMC Services of West Fayetteville

FID #: 011019

County: Cumberland

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

Project: Add 5 dialysis stations for a total of 40 stations upon completion of this project, Project ID #M-11219-16 (relocate 5 stations to BMA Fayetteville), Project ID #M-11225-16 (add 5 stations) and Project ID #M-11286-17 (relocate 5 stations to develop FKC Rockfish).

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

Bio-Medical Applications of North Carolina, Inc. (BMA), d/b/a FMC Services of West Fayetteville (FMC West Fayetteville or the applicant) proposes to add five dialysis stations to the existing facility for a total of 40 stations upon completion of this project and the following projects:

- M-11219-16 Relocate five stations from FMC Services of West Fayetteville to BMA Fayetteville
- M-11225-16 Add five stations to FMC Services of West Fayetteville
- M-11286-17 Develop a new 10 station dialysis facility by relocating five dialysis stations from FMC Dialysis Services South Ramsey Dialysis and five dialysis stations from FMC Services of West Fayetteville

The applicant does not propose to establish new dialysis stations in Cumberland County.

Need Determination

The 2017 State Medical Facilities Plan (2017 SMFP) provides a county need methodology and a facility need methodology for determining the need for new dialysis stations. According to the January 2017 Semiannual Dialysis Report (SDR), the county need methodology shows there is a deficit of eight dialysis stations in Cumberland County. Therefore, the January 2017 SDR does not indicate a need for additional stations in Cumberland County based on the county need methodology, which states that the county deficit must be 10 or greater to establish a need for additional stations. However, the applicant is eligible to apply for additional dialysis stations based on the facility need methodology if the utilization rate for the dialysis center, as reported in the most recent SDR, is at least 3.2 patients per station per week, or 80%. The utilization rate reported for FMC Services of West Fayetteville in the January 2017 SDR is 3.9 patients per station per week, or 97.5%. [$156 / 40 = 3.9$; $3.9 / 4 = 0.975$], based on 156 in-center dialysis patients and 40 certified dialysis stations.

Below is a table that illustrates the facility need for additional dialysis stations at FMC Services of West Fayetteville:

APRIL 1 REVIEW-JANUARY SDR		
Required SDR Utilization		80%
Center Utilization Rate as of 6/30/16		97.50%
Certified Stations		40
Pending Stations		5
Total Existing and Pending Stations		45
In-Center Patients as of 6/30/16 (SDR2)		156
In-Center Patients as of 12/31/15 (SDR1)		151
Step	Description	Result
(i)	Difference (SDR2 - SDR1)	5
	Multiply the difference by 2 for the projected net in-center change	10
	Divide the projected net in-center change for 1 year by the number of in-center patients as of 12/31/15	0.0662
(ii)	Divide the result of step (i) by 12	0.0055
(iii)	Multiply the result of step (ii) by 6 (the number of months from 6/30/16 until 12/31/16)	0.0331
(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	161.1656
(v)	Divide the result of step (iv) by 3.2 patients per station	50.3642
	and subtract the number of certified and pending stations to determine the number of stations needed	5

As shown in the table above, based on the facility need methodology for dialysis stations, the potential number of stations needed is five stations. Step (C) of the facility need methodology states, “*The facility may apply to expand to meet the need established ..., up to a maximum of ten stations.*” The applicant proposes to add five new stations, therefore the application is consistent with the facility need determination for dialysis stations.

Policies

There is one policy in the 2017 SMFP which is applicable to this review. POLICY GEN-3: BASIC PRINCIPLES on page 33 of the 2017 SMFP is applicable to this review because the facility need methodology is applicable to this review. Policy GEN-3 states:

“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

Promote Safety and Quality

The applicant describes how it believes the proposed project would promote safety and quality in Section B-4(a), pages 13 - 15, Section K.1(g), page 52, Section N-1, page 62 and Section O, pages 64 - 66, and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access

The applicant describes how it believes the proposed project would promote equitable access in Section B-4(b), pages 14 - 15, Section C-3, page 21, Section L, pages 56 - 60, Section N-1, page 62, and referenced exhibits. The information provided by the applicant is reasonable and supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes the proposed project would maximize healthcare value in Section B-4(c), page 15, Section C, pages 18 – 24, Section F, Section K and Section N, page 62. The information provided by the applicant with regard to its efforts to maximize healthcare value is reasonable and supports the determination that the applicant’s proposal would maximize healthcare value.

The applicant adequately demonstrates how its proposal incorporates the concepts of quality, equitable access and maximum value for resources expended in meeting the facility need as identified by the applicant. Therefore, the application is consistent with Policy GEN-3.

Conclusion

In summary, the applicant adequately demonstrates that the proposal is consistent with the facility need methodology in the January 2017 SDR and with Policy GEN-3. Therefore, the application is conforming to this criterion.

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

C

The applicant proposes to add five dialysis stations to the existing facility for a total of 40 stations upon completion of this project and the following projects:

- M-11219-16 Relocate five stations from FMC Services of West Fayetteville to BMA Fayetteville
- M-11225-16 Add five stations to FMC Services of West Fayetteville
- M-11286-17 Develop a new 10 station dialysis facility by relocating five dialysis stations from FMC Dialysis Services South Ramsey Dialysis and five dialysis stations from FMC Services of West Fayetteville

Below is a table summarized from page four of the application that illustrates this proposal and other previously approved projects impacting the number of dialysis stations at FMC Services of West Fayetteville:

# STATIONS	DESCRIPTION	PROJECT ID#
40	Total # existing certified stations as of the most recent SDR	
5	# stations to be added as part of this project	
5	# stations previously approved to be added but not yet certified	M-11225-16
-5	# stations previously approved to be deleted but not yet certified	M-11219-16
-5	# stations proposed to be deleted in an application still under review	M-11286-17
40	# stations upon completion of all facility projects	

Patient Origin

On page 373, the 2017 SMFP defines the service area for dialysis services as “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining North Carolina counties is a separate dialysis station planning area.*” Thus, the service area for this facility is Cumberland County. Facilities may also serve residents of counties not included in their service area.

In Section C-8, page 23, the applicant provides a table to illustrate the historical patient origin for in-center patients served by FMC Services of West Fayetteville as of December 31, 2016:

**FMC Services of West Fayetteville
Patient Origin as of 12/31/2016**

RESIDENCE COUNTY	# PATIENTS
Cumberland	144
Hoke	10
Mecklenburg	1
Robeson	7
Sampson	1
Wake	1
Other States	2
Total	166

In Section C.1, page 18, the applicant provides projected patient origin for FMC Services of West Fayetteville for the first two years of operation following project completion, as illustrated in the table below:

COUNTY	OY 1 CY 2019	OY 2 CY 2020	COUNTY PATIENTS AS % OF TOTAL	
			OY 1	OY 2
Cumberland	138.3	145.4	94.5%	94.8%
Hoke	4	4	2.7%	2.6%
Robeson	3	3	2.1%	2.0%
Sampson	1	1	0.7%	0.7%
Total	146.3	149.1 *	100.0%	100.0%

*On page 18, the applicant’s total appears to be an error in calculation; the total is 153.4 [145.4 + 4 + 3 + 1 = 153.4].
Percent totals may not foot due to rounding

The applicant does not state the basis for the projected patient origin for FMC Services of West Fayetteville following the station addition; however, it is an existing facility that has been serving patients. Thus, it is reasonable to conclude that the projected patient origin will derive from the population presently and historically served at that facility. In Section C.1, page 18, the applicant states FMC Services of West Fayetteville is not certified to provide home training. The applicant adequately identifies the population it proposes to serve.

Analysis of Need

In Section B.4, page 13, the applicant states the application is filed pursuant to the facility need methodology in the 2017 SMFP. In Section B.2, page 11, the applicant utilizes data from the January 2017 SDR to apply the facility need methodology to demonstrate how the facility qualifies for five additional stations. In Section C.1, pages 18-19, the applicant provides the following assumptions for projecting in-center patients, summarized as follows:

1. The applicant assumes the Cumberland County dialysis patient population at FMC Services of West Fayetteville will dialyze at a rate equal to the Cumberland County Five Year Average Annual Change Rate (AACR) of 5.2%, published in the January 2017 SDR.
2. In Project I.D. #M-11219-16, BMA proposed to relocate five stations and transfer four Robeson County patients and two additional patients currently dialyzing at FMC West Fayetteville to BMA Fayetteville as of June 30, 2017. BMA continues with those assumptions in this application.
3. In Project I.D. #M-11286-17, BMA proposed to develop a new facility, FKC Rockfish, in Cumberland County by relocating 5 stations from FMC West Fayetteville and 5 stations from FMC North Ramsey. The applicant projected that 22 Cumberland County and six Hoke County dialysis patients would transfer to the new FKC Rockfish facility upon project completion. BMA continues with those assumptions in this application.
4. The January 2017 SDR reports that FMC West Fayetteville facility census was 156 in-center patients as of June 30, 2016. The ESRD Data Collection Form filed in February 2017 indicates that the facility census was 166 in-center patients as of December 31, 2016. The applicant states that 22 of the 166 patients reside in counties other than Cumberland, and notes on page 19 that ten of the 22 will not be carried forward in projections of future patients at FMC Services of West Fayetteville.
5. The applicant states it will add four Hoke County patients, three Robeson County patients, and one Sampson County patient to the facility census after projecting growth of Cumberland County patients.
6. The applicant projects project completion on December 31, 2018; therefore, Operating Year One (OY 1) will be calendar year 2019, and Operating Year Two (OY 2) will be calendar year 2020.

Projected Utilization

In Section C.1, page 20, the applicant provides the methodology used to project in-center utilization. However, the applicant incorrectly applied a 5.6% AACR for Cumberland County in step 5 of the methodology. In a request for clarifying information, the applicant confirmed that the correct AACR should have been 5.2%, pursuant to the January 2017 SDR, as illustrated in the table below.

	FMC SERVICES OF WEST FAYETTEVILLE	IN-CENTER PATIENTS
1	Begin with 144 Cumberland County in-center dialysis patients as of 12/31/2016.	144
2	Project this population forward six months to 6/30/2017.	$[144 \times (0.052 / 12 \times 6)] + 144 = 147.7$
3	Subtract two patients to transfer to Fayetteville Kidney Center	$147.7 - 2 = 145.7$
4	Project this population forward six months to 12/31/2017.	$[145.7 \times (0.052 / 12 \times 6)] + 145.7 = 149.4$
5	Project the Cumberland County patient population forward one year to December 31, 2018, using the Cumberland County Five Year AACR of 5.2%.	$149.4 \times 1.052 = 157.2$
6	Subtract 22 patients to transfer to FKC Rockfish	$157.2 - 22 = 135.2$
7	Project the Cumberland County patient population forward one year to December 31, 2019, using the Cumberland County Five Year AACR of 5.2%.	$135.2 \times 1.052 = 142.2$
8	Add eight patients from Hoke, Robeson and Sampson counties. This is the census for the end of OY 1	$142.2 + 8 = 150.2$
9	Project the Cumberland County patient population forward one year to December 31, 2020, using the Cumberland County Five Year AACR of 5.2%.	$142.2 \times 1.052 = 149.6$
10	Add eight patients from Hoke, Robeson and Sampson counties. This is the census for the end of OY 2	$149.6 + 8 = 157.6$

The applicant states on page 20 that it rounds down to the nearest whole number. The applicant projects to serve 150 in-center patients on 40 stations, or 3.75 patients per station per week ($150 / 40 = 3.75$) by the end of Operating Year 1, and 157 in-center patients or 3.9 patients per station per week ($157 / 40 = 3.93$) by the end of Operating Year 2. This satisfies 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 based on reasonable and adequately supported assumptions regarding continued growth at FMC Services of West Fayetteville.

On page 18, the applicant states FMC Services of West Fayetteville is not certified to provide home dialysis.

Access

In Section L.1, pages 56 - 57, the applicant states that each of BMA’s 108 facilities in 42 North Carolina counties has a patient population which includes low-income, racial and ethnic minorities, women, handicapped, elderly, and other underserved persons.

The applicant projects that 89.45% of the dialysis patients at FMC Services of West Fayetteville will be Medicare or Medicaid recipients in CY 2020, based upon the facility payor mix in FY 2016. The applicant adequately demonstrates the extent to which all residents of the service area, including underserved groups, are likely to have access to its services.

Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population projected to be served has for the proposed services, and demonstrates the

extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services. Therefore, the application is conforming to this criterion.

- (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.

NA

- (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

In Section E, page 26, the applicant describes the alternatives it considered prior to submitting this application for the proposed project, which include:

- Maintain the status quo – The applicant states that maintaining the status quo is not an effective alternative because it ignores the number of patients who reside in the area and choose to dialyze at FMC Services of West Fayetteville. In addition, the applicant states that Cumberland County has the largest ESRD patient population in the state, and that patient population is increasing at a 5.2% rate. Moreover, the January 2017 SDR shows a deficit of eight stations in Cumberland County, which will only be partially addressed by the addition of five stations as proposed in this application.
- Apply for fewer stations - The applicant states this is not an effective alternative. The applicant states that the facility is projected to be utilized at over 90% of capacity; thus, more stations are needed at the facility.
- Relocate five stations from FMC South Ramsey – The applicant acknowledges the low utilization (64.71%) at FMC South Ramsey reported in the January 2017 SDR. However, the applicant states FMC South Ramsey's location proximate to Fort Bragg establishes it as a facility that treats a transient patient population and thus the utilization necessarily fluctuates. The station capacity must be maintained to continue to support this transient population.
- Relocate five stations from FMC North Ramsey – The applicant states the utilization reported in the January 2017 SDR was 3.5 patients per station per week, or 87.5%, which warrants maintaining the number of stations it has.

After considering the above alternatives, the applicant states the proposed project represented in the application is the most effective alternative to meet the identified need for five additional stations at FMC Services of West Fayetteville.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicant adequately demonstrates that the proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and is approved subject to the following conditions.

1. **Bio-Medical Applications of North Carolina, Inc., d/b/a FMC Services of West Fayetteville shall materially comply with all representations made in the certificate of need application.**
 2. **Bio-Medical Applications of North Carolina, Inc. shall develop and operate no more than five additional dialysis stations for a total of 40 certified stations following completion of this project, Project ID #M-11219-16 (relocate five stations to BMA Fayetteville), Project ID #M-11225-16 (add five stations) and Project ID #M-11286-17 (relocate five stations to develop FKC Rockfish) which shall include any home hemodialysis training or isolation stations.**
 3. **Bio-Medical Applications of North Carolina, Inc., d/b/a FMC Services of West Fayetteville 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 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 add five dialysis stations to the existing facility for a total of 40 stations upon completion of this project and the following projects:

- M-11219-16 Relocate five stations from FMC Services of West Fayetteville to BMA Fayetteville
- M-11225-16 Add five stations to FMC Services of West Fayetteville
- M-11286-17 Develop a new 10 station dialysis facility by relocating five dialysis stations from FMC Dialysis Services South Ramsey Dialysis and five dialysis stations from FMC Services of West Fayetteville

Capital and Working Capital Costs

In Section F.1, page 28 and Section F.10, page 32, the applicant states that there are no capital costs or working capital needs associated with the proposed project.

Availability of Funds

In Exhibit F-1, the applicant provides a letter dated March 15, 2017 from the Senior Vice President & Treasurer of the parent company, Fresenius Medical Care Holdings, Inc. (FMC), authorizing the project as proposed. Exhibit F-2 contains the FMC and Subsidiaries Consolidated Financial Statements, as of December 31, 2015, showing cash and cash equivalents of \$249,300,000, total assets of \$19,332,539,000 and net assets (total assets less total liabilities) of \$10,144,288,000. The applicant adequately demonstrates the availability of funds for the operating needs of the project.

Financial Feasibility

In Section R of the application, the applicant provides pro forma financial statements for the first two years of the project. In the pro forma financial statements (Form B), the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

PROJECTED REVENUES AND OPERATING EXPENSES		
FMC SERVICES OF WEST FAYETTEVILLE	OPERATING YEAR 1 CY 2019	OPERATING YEAR 2 CY 2020
Total Treatments	22,152	23,244
Total Gross Revenues (Charges)	\$86,923,472	\$88,059,028
Total Net Revenue	\$ 5,195,694	\$ 5,451,726
Total Operating Expenses (Costs)	\$ 5,164,997	\$ 5,353,424
Net Income	\$ 30,697	\$ 98,302

In Form C, page 79, the applicant's projections of the number of treatments to be provided is inconsistent with the projections of the number of patients to be served that the applicant described in Section C. However, the applicant's projections of the number of patients to be served and the number of dialysis treatments to be provided were understated as a result of mathematical errors. Since the projections of revenues and expenses were understated and the applicant projects a positive net income, the project is nevertheless financially feasible. See Section R of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based on reasonable projections of costs and charges.

Conclusion

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital and operating needs of the proposal and that the financial feasibility of the project is based on reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

- (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 add five dialysis stations to the existing facility for a total of 40 stations upon completion of this project and the following projects:

- M-11219-16 Relocate five stations from FMC Services of West Fayetteville to BMA Fayetteville
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- M-11286-17 Develop a new 10 station dialysis facility by relocating five dialysis stations from FMC Dialysis Services South Ramsey Dialysis and five dialysis stations from FMC Services of West Fayetteville

On page 373, the 2017 SMFP defines the service area for dialysis services as “*the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty Planning Area, each of the 94 remaining North Carolina counties is a separate dialysis station planning area.*” Thus, the service area for this facility is Cumberland County. Facilities may also serve residents of counties not included in their service area.

The applicant currently operates four dialysis centers in Cumberland County, and is the only provider of dialysis services in the county. All of the facilities are located in Fayetteville. See the following table:

Utilization BMA Cumberland County Facilities / January 2017 SDR

FACILITY NAME	# STATIONS	# PATIENTS	% UTILIZATION
Fayetteville Kidney Center	39	139	89.10%
FMC North Ramsey	40	140	87.50%
FMC South Ramsey	51	132	64.71%
FMC West Fayetteville	40	156	97.50%

Source: January 2017 SDR, Application page 53

As shown in the table above, three of the four Cumberland County dialysis facilities are operating above 80% utilization (3.2 patients per station); in fact, those facilities are operating above 85% utilization. One facility, FMC South Ramsey, is operating below 70% utilization.

According to Table B in the January 2017 SDR, there is a deficit of eight dialysis stations in Cumberland County. The applicant proposes to add five stations to a facility that was operating at 97.5% of capacity in the January 2017 SDR. By adding five stations to the county complement of dialysis stations, the applicant will reduce the deficit by five. Therefore, it is not duplicating dialysis services in Cumberland County.

In Section C.1, page 20, the applicant demonstrates that FMC Services of West Fayetteville will serve a total of 150 in-center patients on 40 dialysis stations at the end of the first operating

year, which is 3.75 patients per station per week, or a utilization rate of 93.7% [$150 / 40 = 3.75$; $3.75 / 4 = 0.9375$]. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

The applicant adequately demonstrates the need to add five stations to FMC Services of West Fayetteville. The discussion on analysis of need found in Criterion (3) is incorporated herein by reference.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities in Cumberland County. Consequently, the application is conforming to this criterion.

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

C

In Section H, page 41, the applicant provides the following table to illustrate projected staffing in full time equivalents (FTEs) for FMC Services of West Fayetteville. The applicant does not propose to add additional FTEs when the stations are added. The applicant states the Medical Director is not directly employed by the facility, and thus is not reflected on the staffing chart.

POSITION	# FTEs
Registered Nurse	9.00
Technician (PCT))	21.00
Clinical Manager	1.00
Administrator	0.25
Dietician	1.00
Social Worker	1.00
Chief Tech	0.25
Equipment Tech	0.75
In-Service	0.25
Clerical	1.50
Total	36.00

In Section H.7, page 44, the applicant provides the projected direct care staff for the proposed facility in OY 2 (CY 2020), as shown in the table below:

DIRECT CARE POSITIONS	# FTEs	HOURS PER YEAR PER FTE	TOTAL ANNUAL FTE HOURS	TOTAL ANNUAL HOURS OF OPERATION	# FTE HOURS PER HOUR OF OPERATION
Registered Nurse	8.00	2,080	16,640	5,070	3.28
Technician (PCT)	17.00	2,080	35,360	5,070	6.97
Total	25.00	2,080	52,000	5,070	10.26

In Section H.6, page 43, the applicant states dialysis services will be available from 6:00 AM to 5:00 PM, Monday through Saturday, for a total of 11 hours per day / 66 hours per week. In addition, the applicant states the facility routinely offers nocturnal dialysis three times per week

for patients who prefer that shift, from 6:30 PM to 5:30 AM, or an additional 31.5 hours per week.

In Section I.3, page 47, the applicant identifies Dr. Richmond Nuamah as the current and continuing Medical Director of the facility. In Exhibit I-5, the applicant provides a copy of a letter signed by Dr. Nuamah supporting the project and confirming his commitment to continue to serve as Medical Director. In Section H.3, page 42, the applicant describes the methods used to recruit and fill positions at the facility.

The applicant documents the availability of adequate health manpower and management personnel, including the Medical Director, for the provision of the proposed dialysis services. Therefore, the application is conforming to this criterion.

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

C

In Section I.1, page 45, the applicant identifies the necessary ancillary and support services that serve FMC Services of West Fayetteville. Exhibit I-5 contains a letter from the medical director of the facility expressing his support for the proposed project. The applicant discusses coordination with the existing health care system on pages 47 - 48. Exhibits I-1 through I-4, respectively, contain copies of agreements for home training, lab services, acute services and transplantation services. The applicant adequately demonstrates that the necessary ancillary and support services will be available and that the proposed services will be coordinated with the existing health care system. Therefore, 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

- (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

(11) Repealed effective July 1, 1987.

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

NA

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

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

C

In Section L.7, page 60, the applicant provides the historical payor mix for FMC Services of West Fayetteville for CY 2016, as shown below:

PAYMENT SOURCE	PERCENT OF TOTAL PATIENTS
Self-Pay / Indigent / Charity	-.07%
Medicare	74.13%
Medicaid	5.14%
Commercial Insurance	5.78%
Medicare Commercial	12.01%
Miscellaneous (Incl. VA)	3.02%
Total	100.00%

Totals may not sum due to rounding

In Section L-7, page 60, the applicant states the negative amount listed as “*self pay/indigent/charity*” in the table is merely an accounting function rather than a number based on patients. The applicant states that during CY 2016 a “*very small*” number of treatments were incorrectly coded as “*self pay*” which, when corrected by the applicant reflects as a negative number.

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

Percent of Population						
County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
Cumberland	11%	51%	55%	18%	11%	16%
Statewide	15%	51%	36%	17%	10%	15%

Source: <http://www.census.gov/quickfacts/table>, 2014 Estimate as of December 22, 2015.

*Excludes “*White alone*” who are “*not Hispanic or Latino*”

**“*This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable.*”

The IPRO ESRD Network of the South Atlantic Network 6 (IPRO SA Network 6) consists of North Carolina, South Carolina and Georgia. IPRO SA Network 6 provides a 2015 Annual Report which includes aggregate ESRD patient data from all three states. However, a comparison of the *Southeastern Kidney Council Network 6 Inc. 2014 Annual Report*¹ percentages for North Carolina and the aggregate data for all three states in IPRO SA Network 6 shows very little variance; therefore the statistics for IPRO SA Network 6 are representative of North Carolina.

The IPRO SA Network 6 provides prevalence data on dialysis patients by age, race, and gender in its 2015 annual report, pages 27-28². In 2015, over 85% of dialysis patients in Network 6 were 45 years of age and older, over 67% were non-Caucasian and 45% were female. (IPRO SA Network 6).

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;

¹<http://esrd.ipro.org/wp-content/uploads/2016/06/2014-Network-6-Annual-Report-web.pdf>

²<http://esrd.ipro.org/wp-content/uploads/2016/11/2015-NW-6-Annual-Report-Final-Draft-with-COR-Changes-Submitted-11-29-2016.pdf>

C

In Section L.3(e), page 59, the applicant states “*BMA of North Carolina facilities do not have any obligation to provide uncompensated or community service under any federal regulations*” In Section L.6, page 60, the applicant states “*There have been no Civil Rights complaints lodged against any BMA North Carolina facilities in the past five years.*” 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.1, page 57, the applicant states: “*It is BMA 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.1(b), page 57, the applicant projects that 89.45% of all patients in CY 2020 (OY 2) will have all or part of their services paid for by Medicare and or Medicaid, as shown in the table below:

PAYMENT SOURCE	PERCENT OF TOTAL PATIENTS
Self-Pay / Indigent / Charity	1.03%
Medicare	72.79%
Medicaid	4.37%
Commercial Insurance	6.32%
Medicare Commercial	12.29%
Miscellaneous (Incl. VA)	3.20%
Total	100.00%

The projected payor mix is based on the historical payor mix of FMC Services of West Fayetteville. The applicant adequately demonstrates that medically underserved populations will have access to the proposed services. Therefore, 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.4, page 59, the applicant states, “*Those Nephrologists who apply for and receive medical staff privileges will admit patients with End Stage Renal Disease to the facility. [FMC Services of West Fayetteville] has an open policy, which means that any Nephrologist may apply to admit patients at the facility. The attending physicians*

receive referrals from other physicians or Nephrologists or hospital emergency rooms.” The applicant adequately demonstrates that FMC Services of West Fayetteville offers a range of means by which a person can access dialysis services. Therefore, 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.1, page 77, the applicant states, “*BMA has communicated with the local student nursing programs encouraging those programs to utilize the resources of the [FMC Services of West Fayetteville] facility to enhance the educational opportunities for the nursing student.*” In Exhibit M-1, the applicant provides a copy of a letter to Fayetteville Community College inviting the nursing students to include FMC Services of West Fayetteville in their clinical rotations. The information provided in Section M and referenced exhibits is reasonable and credible and supports a finding of conformity to this criterion.

- (15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to add five dialysis stations to the existing facility for a total of 40 stations upon completion of this project and the following projects:

- M-11219-16 Relocate five stations from FMC West Fayetteville to BMA Fayetteville
- M-11225-16 Add five stations to FMC Services of West Fayetteville
- M-11286-17 Develop a new 10 station dialysis facility by relocating five dialysis stations from FMC Dialysis Services South Ramsey Dialysis and five dialysis stations from FMC Services of West Fayetteville

On page 373, the 2017 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.*” Thus, the service

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

The applicant currently operates four dialysis centers in Cumberland County, and is the only provider of dialysis services in Cumberland County. All of the facilities are located in Fayetteville. See the following table:

Utilization BMA Cumberland County Facilities / January 2017 SDR

FACILITY NAME	# STATIONS	# PATIENTS	% UTILIZATION
Fayetteville Kidney Center	39	139	89.10%
FMC North Ramsey	40	140	87.50%
FMC South Ramsey	51	132	64.71%
FMC West Fayetteville	40	156	97.50%

Source: January 2017 SDR, Application page 53

As shown in the table above, three of the four Cumberland County dialysis facilities are operating above the statutory minimum 80% utilization (3.2 patients per station); in fact, those facilities are operating above 85% utilization. One facility, FMC South Ramsey, is operating below 70% utilization. The average utilization rate for the 170 existing Cumberland County stations is 83.4% [567 patients / 170 stations = 3.33; 3.33 / 4 = 83.4%].

In Section C, pages 18 – 20 and clarifying information provided at the Agency’s request, the applicant demonstrates that FMC Services of West Fayetteville will serve a total of 150 in-center patients at the end of OY 1 (CY 2019), for a utilization rate of 93.75% [150 / 40 = 3.75; 3.75 / 4 = 0.9375]. The projected utilization of 3.75 in-center patients per station per week satisfies the 3.2 in-center patients per station per week threshold as required by 10A NCAC 14C .2203(b).

In Section N.1, page 78, the applicant discusses how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed services.

The information provided by the applicant in the sections referenced above is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on the cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application, and the following analysis:

- The applicant adequately demonstrates the need for the proposed project and that it is an effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that FMC Services of West Fayetteville will provide quality dialysis services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.

- The applicant demonstrates that FKC Rockfish will provide access to medically underserved populations. The discussions regarding access found in Criteria (1), (3), and (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

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

C

In Section B.1, pages 14 - 16, Section O, pages 64 - 67 and Exhibit O-1, the applicant discusses the methods it uses to ensure and maintain quality in its dialysis facilities.

In Section O.3, pages 67 – 68, the applicant states that out of more than 100 facilities located in North Carolina operated by the applicant or a related entity, only the two listed below were not in compliance with Medicare conditions of participation during the 18 months prior to submission of the application.

BMA QUALITY CARE			
FACILITY	SURVEY DATE	BACK IN COMPLIANCE	
BMA East Rocky Mount	01/15/2017	Yes	03/01/2017
RAI West College-Warsaw	3/15/2016	Yes	4/13/2016

Source: Information provided in Application Exhibit O-3

Based on a review of this certificate of need application and publicly available information, the applicant adequately demonstrates that it has provided quality care during the 18 months immediately preceding the submittal of the application through the date of the decision. The application is conforming to this criterion.

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

C

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

10A NCAC 14C .2203 PERFORMANCE STANDARDS

(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-

(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 C-1, pages 18 – 20, the applicant projects that FMC Dialysis Services of West Fayetteville will serve a total of 150 in-center patients at the end of OY1 (CY 2019) which is 93.75% or 3.75 patients per station per week [150 patients / 40 stations = 3.75; $3.75 / 4 = 0.9375$].

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

-C- In Section C, pages 18 - 20, 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.